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(72) Inventors; and

(71) Applicants: **ARNO', Matteo** [IT/IT]; Via Villaggio Spotorno 146, 17027 Pietra Ligure (SV) (IT). **IVALDI, Diego** [IT/IT]; Via Olle Superiore 1e, 17024 Finale Ligure (SV) (IT).

(74) Agent: **KARAGHIOSOFF, Giorgio A.**; c/o Studio Karaghiosoff e Frizzi, Via F. Baracca 1r, 17100 Savona (IT).

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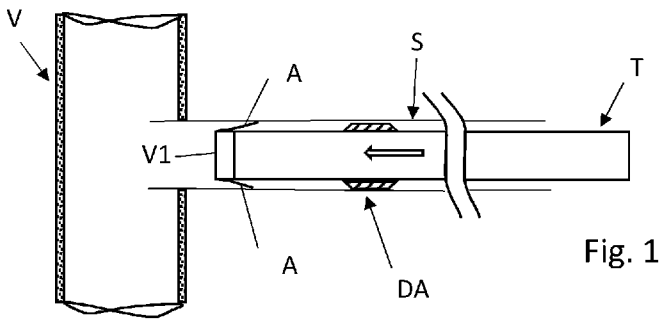

Fig. 1

(57) Abstract: Permanent venous access device, for allowing the connection between an access vein and the skin, usable in particular in the dialysis treatments, that allows disposable catheters to be used. Said device essentially comprises: - a tube, generally a plastic one, having the function of subcutaneous tunnel; - which tube has anchoring means at least at the graft end in a vessel; - a valve, next to at least said graft end; - which tube has an end outside of the body; - anchoring means for the anchorage to the skin and applicable from the outside of the body; - subcutaneous anchoring means and - at least one valve inserted at said tube end, which has to be positioned outside of the skin.

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Matteo Arnò and Diego Ivaldi

PERMANENT VENOUS ACCESS DEVICE, SPECIFICALLY USABLE IN DIALYSIS TREATMENTS.

TEXT OF THE DESCRIPTION

The present invention relates to a permanent venous access device, for allowing the connection between an access vein and the skin, usable in particular in dialysis treatments, and which device allows disposable catheters to be used.

In order to carry out the hemodialysis treatment the patient blood has to flow through an apparatus (dialysis apparatus or artificial kidney) that, with a convenient pump system, circulates the blood through a cleansing filter and returns it to the patient.

Therefore, the blood has to be withdrawn from the patient by positioning a catheter in a large venous vessel (central venous catheter) or an arteriovenous fistula, i.e. a surgically made conjunction, can be set up between a vein and an artery, usually at the arm.

The large arterial vessel used for the dialysis can be the jugular vein (in the neck), the subclavian vein (behind the clavicle) or the femoral vein (in the groin).

At the beginning of the dialysis session the patient is connected (either by needles positioned in the fistula or through the venous catheter) to the

hemodialysis apparatus, then a heparin dose is usually injected, which prevents the blood from clotting in the extracorporeal circuit.

In not rare instances two catheters can be implanted in the same vein (dual lumen catheter), which renders performing dialysis more straightforward, since one lumen serves for withdrawing the blood continuously and the other one for returning the blood inside: with a single catheter (one lumen catheter), the blood has to exit first and re-entering then through the same path.

The catheters presently used for the dialysis cause, in the medium- or long-term, major issues on the veins themselves.

Over time in fact blood flow reductions can be shown due to thrombosis or fibrin build-ups. Unblocking manoeuvres and/or the catheter replacement can be carried out in order to ensure the blood flow, fibrinolytic or anti-coagulant drugs could be used and, in this case, laboratory clotting checks could be required.

At the time the catheter is no longer working the catheter has to be removed, but the vein in which the catheter itself was implanted could be no longer usable.

All of this involves further management expenses since either other part of the patient venous asset has to be used, until it collapses, or a surgical arteriovenous fistula has to be built in the arm so as to allow the patient dialysis.

Object of the present invention is to create a permanent venous access without inserting a catheter within the vein, so as to avoid any complications

related to a permanent catheter, rather a disposable catheter (for single use only).

We found that by creating a subcutaneous tunnel able to allow the connection between the vein and the outside of the body, at least double-valved, i.e. provided with two valves so as to not allow the passage of blood fluids from the vein to the outside, in which tunnel a disposable catheter is inserted to perform a "temporary" dialysis in a permanent and stationary tunnel, the above described drawbacks can be removed or at least significantly reduced, thus obtaining significant reductions in managing costs and/or preservations of the venous asset of the patient under dialysis.

The permanent venous access device, object of the present invention, for allowing the connection between an access vein and the skin, usable in particular in the dialysis treatments, essentially comprises:

- a tube, generally a plastic one, having the function of subcutaneous tunnel;
- which tube has anchoring means at least at the graft end in a vessel;
- a valve, next to at least said graft end;
- which tube has an end outside of the body;
- anchoring means for the anchorage to the skin and applicable from the outside of the body and
- at least one valve, inserted at said tube end, to be positioned outside of the skin.

According to an advantageous improvement, at least the valve provided at the graft end of the vessel is mounted so that it can be disassembled from

the graft end of the tube, withdrawn therefrom and replaced with another valve.

According to a further improvement, both valves are mounted to the tube so that they can be disassembled and withdrawn therefrom and replaced.

In a specific embodiment, the invention provides a device according to one or more of the above described characteristics, and wherein at the graft end of the tube there is an annular seat for the coupling of a circular-shape valve body, which valve seat is firmly fastened to the tube itself, either is made in one piece and made of the material of the tube itself or it can be applied by removable couplings to the tube itself, said annular seat and said valve body being provided with removable mutual fastening means.

Still according to a further improvement, the invention provides that the valve body has at least one pair of removable coupling elements to be rotationally coupled with coupling members of an extractor.

The extractor may be of known type and used for example in laparoscopic surgery.

Generally, the extractor comprises an elongated tubular body having an outside diameter of the order of magnitude of a catheter which is suitable for passing through the tube, and in which elongated tubular body, flexible control rods of push-pull type or rotary ring-nut type are housed and control removable coupling members for the removable coupling with the valve body at the end of said elongated tubular body so that, by acting on a pushing and pulling member or rotational member provided at the

external or distal end of said elongated tubular body which is outside the tube, said coupling members are alternately moved in radial and rotational engagement condition to engage with the valve body by fitting into a corresponding coupling seat provided in the valve body and in disengagement condition disengaged from said coupling seats.

The coupling seats in the valve body may be at least two seats in angularly different positions, preferably diametrically opposite, or three or more seats angularly deployed along the perimeter of the valve body with an angular positioning between each pair of said seats corresponding to the relative angular position of at least two coupling members of the extractor.

The tube having the function of subcutaneous tunnel, that can be in general a plastic one, must have a section such to allow the introduction in the tube itself of a temporary disposable, preferably double lumen, catheter.

In an embodiment, said tube having the function of subcutaneous tunnel will have thus a diameter of at least about 12F (French).

According to a further feature, said tube has subcutaneous anchoring means, such as for example a so-called fibrin cuff, in at least one intermediate area between the vein and the skin.

This cuff is typically in the form of a band wrapped around the outer wall of the tube, in an area comprised between the vein and the skin.

The head of the tube to be anchored to the access vein wall has a valve that is preferably selected among those usually employed in similar

devices and, in particular, is selected so that said valve can be mechanically or autonomously opened and closed, when the catheter will be inserted in the tube having the tunnel function, and allows making permanent the tube itself, once it has been put in traction to the vein wall.

It is possible to provide different types of valves including, but not limited to, non-return-type diaphragm valves or valves comprising shutters shaped so as to be similar to the structure of mitral valves.

According to one or more embodiment variations, said valve could be a check valve, preferably a diaphragm valve.

According to an embodiment, preferably the valve to be positioned outside of the skin can be a mechanical valve, such as in particular a membrane valve or a diaphragm valve.

According to an embodiment, the outer valve can be made similarly to the valve provided on the inner end of the tube.

According to an embodiment, the external valve is sealingly connected to the tube through an external fastening fitting placed on the ending length of the tube having the tunnel function.

An embodiment variation provides for said connection occurring by means of a fitting of the clamping type and composed of a ring nut with conical inner clamping surface and of a threaded cylindrical length cooperating with a clamping end with a conical length intended to cooperate with the conical length of the ring nut, the tube ending length being clamped between the said two conical lengths.

The valve is housed in a tubular length ending on the opposite side thereof with respect to the ring nut with a threaded termination to which a closing cap can be sealingly screwed.

Said closing cap would be usually applied when the device is not operating, i.e. when the catheter is not inside the tube itself.

In addition to the device according to the invention, in order to make the device itself fixed and stationary on the outside and on the skin, at least one external skin anchoring device will have to be provided.

The external skin anchoring device having the function of stationary fastening the tube having the tunnel function, so as to prevent the displacement by unintended tractions of the tube itself, can be of one of the types usually employed for fastening catheters or cannulae in general on the skin ("suture-less") or it could be carried out with stitches.

In particular, it can be a little skin fastening anchor (to be kept generally for at least 30 days after the device insertion) or a fastening device to fasten the long-term accesses already on the market (Broviac, Hickman (fin-less), Groshong (with fin), Statlock, external bumpers, etc.).

The external fastening fitting can consist of a sleeve with threaded termination fitted on the ending length of the tube and the threaded male fitting to screw the sleeve containing the valve positioned outside of the skin.

The procedure for grafting the claimed device can be substantially carried out by the technique

termed Seldinger: it is an inserting technique which is carried out by puncturing and positioning of vascular guide. At least one dilator is passed on the guide by an external sheath that is then removed by peeling it away.

The procedure for grafting the venous access device essentially comprises:

- percutaneously needle puncturing the access vein, with ultrasound guide;
- introducing and positioning the guide wire;
- inserting the peel away dilator on the metal guide wire;
- removing the dilator, by keeping the "peel away" in position;
- inserting and putting into traction the tube having the tunnel function up to the vein wall and subsequently fastening the anchoring valve to the wall itself, upon "peel away" removal;
- Subcutaneous tunneling of part of the tube and the subcutaneous anchoring device (fibrin cuff) according to current techniques;
- at the outer end of the tube having the tunnel function, introducing a fastening fitting containing the valve to be positioned outside of the skin and a closing means at the end of the fastening fitting itself;
- fastening the tube having the tunnel function to the skin by using an adhesive "suture-less" anchoring system or formed with a little skin fastening anchor previously implanted or by stitches.

The dialysis treatment can be carried out in the following way:

- opening the venous access device according to the invention by unscrewing the cap placed at the outer end of the device itself and opening the mechanical valve preferably of diaphragm type contained in the fastening fitting;
- introducing, through the fastening fitting, a preferably double lumen catheter in the tube having the tunnel function of the device and positioning its apex at the passage level of the superior vena cava-right atrium. Centimeter markers will be provided as a reference on the disposable catheter for external reference. During the first implant the suitable length will be communicated by the installers;
- connecting the catheter inserted into the dialysis system and starting the treatment;
- at the end of the dialysis, after the positive pressure washing, closing the valve anchored on the access vein wall, removing or taking the catheter out of the tube having the tunnel function, closing the valve contained in the fastening fitting and screwing the closing means at the fastening fitting end.

A further object of the present invention is an aid kit for aiding the dialysis treatment comprising at least:

- one venous access device as described above in the different variations;
- at least one catheter, preferably a set of preferably double lumen disposable catheters

with curves and lengths differing depending on the access site;

- a venipuncture needle;
- a guide wire;
- at least one dilator, preferably a dilator set;
- a peel away dilator.

Still according to another exemplary embodiment of the kit, said kit comprises at least one or more valves for replacing at least the valve provided at the end of the tunneling coupling tube to be coupled to the vein or to another vessel, at least one extractor tool for the release from the tube and the withdrawal of the valve on the its inner end and for inserting and locking in place a replacement valve on said inner end of the tube, as well as a cap of the tube end outside of the skin, i.e. the distal end of the tube, which cap either comprises a passage way able to be opened or is a replacement cap to replace a closing cap of said tube with said passage way for the elongated body of the withdrawal and replacement tool for replacing and withdrawing the valve.

According to a further characteristic the kit comprises a narrowing device to narrow the tube length outside the skin applicable so as to be detachable or so that it can be activated and deactivated.

These and other characteristics and advantages of the present invention will be more evident from the following description of some exemplary embodiments illustrated in the attached drawings in which:

- fig. 1 shows the introduction of the tube and the valve on the access vein wall (inner fitting);
- figure 2 shows the tube positioning with the head in the position anchored to the vein wall after the dilator has been withdrawn;
- fig. 3 shows the tube and valve anchorage;
- fig. 4 shows the anchored tube, the fastening element (E) and the fastening fitting (R) (outer fitting) placed outside the skin with the outer fastening valve (membrane valve or diaphragm valve).
- Figure 5 schematically shows an exemplary embodiment of a removably coupling of the tube to the valve seat at the inner end of the tube, i.e. at the tube end anchored to the valve.
- Figure 6 shows a view according to figure 4 in which, through the tube T, an extractor tool of the valve 20 is passed, the valve being provided at the tube end anchored to the vein.
- Figure 7 shows an enlarged schematic view of an example of extractor according to figure 6.
- Figures 8 and 9 each show a cross section in the area of the housing seat of the valve and of the valve housed therein, respectively with the positioned valve free from the seat and with the positioned valve locked in said seat.
- Figures 10 and 11 show sections taken along an axial plane respectively denoted by the line X-X of Figure 8 and the line XI-XI of Figure 9.

Fig. 1 shows the introduction of the tube (T) into the valve seat in which a valve is mounted, the valve assembly together with the valve seat being

indicated by V1. The end of the tube and in particular the valve seat has fastening fins A still folded. The introduction takes place through the skin C and on the access vein A by means of a peel away sheath S.

In figures 2 and 3, the tube is brought with the head inside the vein V in such a position to allow, once the peel away dilator has been taken out, the fins A broadening and sealingly anchoring the tube head with the seat and the valve V1 inside the vein itself.

In fig. 3 the head with the seat and the valve V1 and with the umbrella-opened anchoring fins after the vein puncturing is shown, upon the peel away sheath removal.

Fig. 4 shows the tube T inserted and anchored by means of the fins A to the vein V and the skin fastening element E. Fig. 4 also further schematically shows the valve V2 with the fastening fitting consisting of the threaded sleeve M1 and the threaded male fitting M2 for screwing the sleeve itself, on which male fitting the valve V2 (which according to a non-limiting example is a membrane or diaphragm valve) is inserted. . At the end of the male fitting there is the cap P, as closing means.

In case the dialysis catheter has to be introduced, the tube is opened by removing the cap P and the catheter can be inserted through the two membrane or diaphragm valves, thus entering the vein V.

Alternatively, as shown in Figure 6, the cap P may have a passage opening that can be opened or else an additional cap P is provided with a passage

opening, which is mounted in place of the fully closed cap P as shown in figure 4.

When the operation is ended, the catheter can be withdrawn and the tube can be subjected to washing. The tube is then filled up with saline and the cap is applied again.

Since it may be necessary to replace the valve provided at the tube end connecting to the vein V, the invention provides that said valve is removably mounted to a seat therefor which is fastened at the end of the tube.

The valve seat provided at the end of the tube T and intended for coupling with the vein V may be constituted either by an element permanently fastened at the tube end or by an element made in one piece with the tube end or else by a removable element mounted at the tube end.

According to the latter embodiment, the tube can be detachably coupled, through screw means, to the valve seat which has the anchoring fins for anchoring to the vein wall coupled thereto and so acts as a tube anchoring head, the screw means allowing the tube to be detached from said valve seat by rotating the tube itself around its axis.

In the embodiment schematically shown in Figure 5, the valve seat, acting as head for the anchoring to the vein and to which the diaphragm valve is removably coupled, has a jointing sleeve with an outer thread. This threaded jointing sleeve F is intended to be engaged within the end of the tube T by a screwing action, during which the thread dilates and at least partially incises or deforms the tube wall thus generating a mechanical coupling that

stands a certain traction force, surely larger than that required for the operations of implantation of the tube itself and anchorage to the vein. In order to take the tube out, once the subcutaneous anchoring cuff has been removed, it is sufficient to rotate the tube T in the unscrewing direction and thus, once the end of the same is free from the anchoring head, the tube can be taken out. Many different implementations are possible, as well as many variations are also possible with respect to the illustrated threaded solution. In the illustrated embodiment the thread is not exclusively helical, but also conical; this is only an example and should not be construed as a limiting feature.

Referring to figures 8 to 11, they show enlarged views of structural detail of an exemplary embodiment of valve seat and removable valve.

Figures 8 and 9 are cross sections of the tube in the region of the valve seat and the valve, taken along planes perpendicular to the axis of the tube and with the valve positioned in the seat where the valve is freely oriented with respect to the seat as regard an axially away movement or axially approaching movement and in the position where the valve is locked to the valve seat.

In this exemplary embodiment, the locking and unlocking movement occurs by rotating the valve with respect to the seat around an axis parallel to or coincident with the axis of the tube.

Figures 10 and 11 are enlarged sections of the inner ending portion of the tube carrying the valve seat and the valve, with respect to the axial section plane defined by the X-X line in Figure 8 and the XI-

XI line in Figure 9, respectively.

Referring to the above said figures, the valve seat denoted by numeral 10 is made in the form of an annular element having a recessed annular radial shoulder 110 forming an axial support for the circular valve body denoted by numeral 20. Both the valve seat and the valve have circular symmetrical shapes and are coaxial with each other.

The valve seat has pairs of recesses 210 open on the radially inner cylindrical wall of a cylindrical portion 310 of said valve housing seat, and which have angular positions different from each other, preferably diametrically opposite from each other, along the inner circumference. A circle of one or more of said recesses 210 deployed along the inner circumference of the cylindrical portion of the valve seat can be also provided. The recesses 210 have a predetermined length corresponding to a predetermined angular width of an arc of a circle. These recesses or niches in the cylindrical wall 310 of the housing seat 10 of the valve 20 have an opening 410 along a certain portion of their length, at the head side of the cylindrical wall 310 of the seat 10 opposite to the annular shoulder 110 and facing the tube end outside the skin. These openings 410 are openings for inserting and withdrawing radial engaging fins 120 projecting from the body of the valve 20, through which said fins 120 are led to a position coincident with the niches or recesses 210 and can be moved to the engagement position inside them, thereby generating both an axial constraint locking the valve 20 in the seat 10 and a stop for the angular displacement of the fins inside the recesses 210

through which the valve is reversibly and removably locked in the seat 10.

The radial and circumferential extensions of the openings 410 on the head side are greater than or equal to the corresponding dimension of a corresponding outer radial fin 120.

In the embodiment shown, the valve 20 has a pair of fins 120 arranged in different angular positions along the outer cylindrical wall of the body of the valve 20 and which, in the depicted exemplary embodiment, are diametrically opposite to each other. Each of these fins 120 cooperates with a corresponding recess 210, although the valve 20 may also have three or more radial fins 120 and the valve seat may have a corresponding number of recesses 210 and openings 410 and/or even a greater number of said recesses 210 and combined openings 410 with respect to the number of fins 120 on the valve 20.

As can be seen from the figures, the valve 20 has a disc-shaped body having circular shape coaxial with the seat 10 and an outer diameter slightly smaller than the inner diameter of the annular seat 10 of the valve, but greater than the inner diameter of the annular shoulder 110 of the seat of the valve itself.

In the exemplary embodiment, the valve 20 comprises an annular, cylindrical wall 220 defining a central passage 320 and having an annular cylindrical wall whose radially external side has outwardly extending engaging fins 120 for the engagement with the valve seat 10.

The passage 320 can be opened and closed by a shutter 420 symbolically shown in the figure.

As already mentioned above, various types of shutters may be provided such as for example, and not exclusively, shutters consisting of diaphragms or lamellae that co-operate with each other as a mitral check valve. An example of these valves is described in document US3445916 or US4222126.

Still referring to Figures 8 to 11, in the annular, cylindrical wall, at least one pair of radial recesses 520 are provided which are open at the radially inner wall and have a predetermined angular and axial width. There are at least two recesses provided in angular positions different, preferably diametrically opposite, from each other. Said recesses 520 are intended to cooperate with coupling members 150 of an extractor 50, which members can be alternatively driven in a radially withdrawn position in which they fit into said recesses thus generating both a rotational coupling of the annular part 220, and therefore of the valve 20, with said members and a locking to said members also in the axial direction of the tube T and in a radially retracted position in which they do not interfere with the annular part 220 of the valve 20 and are decoupled therefrom.

In the example shown, the members consist of terminations 1250 of flexible leaves 350 which can be alternately moved away and close to each other through control means 450 provided on the extractor 50 at the end thereof outside the tube T.

In the example depicted, the extractor has a flexible and elongated body consisting of a tubular sheath 550 in which push-pull actuators 560 are housed which have the leaves 250 connected to one of

their ends and a pushing/pulling member 450, outwardly protruding from said sheath 550, connected to the opposite end.

The ends 1250 of the flexible leaves 250 cooperate with a deflector diverting element 570 interposed between them and causing said leaves to bend from the axial to the radial direction since said ends 1250 are provided at corresponding side openings in the sheath 550 through which said terminations are radially moved outwards and inwards.

Figure 7 shows a schematic view of this extractor.

Figure 6 shows the extractor inserted through a cap passage and in coupling position with the valve 20 at the inner end of the tube.

It is clear that, to release the valve 20 from the housing seat 10, at the end of the tube T the extractor is fitted through a passageway of the cap P and the operating head of the extractor is led inside the annular wall 220 of the valve 20. By applying a pressure on the pushing/pulling member 450, the terminations 1250 are radially pushed outwards and by applying a simultaneous rotation around the axis of the extruder sheath, the engagement members, i.e. the terminations 1250, are rotated and brought at the recesses 520 in which they can enter thanks to a further pushing action on the pushing/pulling member 450.

By maintaining the pressure on said member 450, the valve 20 can be rotated so as to bring the outer radial fins 120 from the locked position, within the recesses 210 of the seat 10, to the released position in which the fins coincide with the openings 410. In

this position the valve 20 can be axially detached from the seat 10 and then withdrawn through the tube. When the valve is in the tube length outside the skin, the tube T can be narrowed at the length between the skin and the position of the valve 20. Then, the termination can be detached by acting on the joint M1. Then, the valve can be completely removed from the T tube without risking the leakage of blood liquids. A new valve can be mounted on the extractor's operating head and then inserted into the tube T. The joint is then tightened again on the tube T. By removing the narrowing of the tube the new valve 20 can thus be brought into the seat 10. By rotating the extractor, the fins 120 of the new valve 20 can be led at the openings 410 for the axial insertion into the recesses 210 and then, by fitting the extractor further into the tube T, the fins 120 are inserted into the openings 410 up to coincide with the recesses 210 and then, by rotating the extractor, the fins are led to the locking state to be locked in the recesses 210. By pulling the pushing and pulling member 450 of the extractor, the terminations 1250 are radially retracted from the recesses 520 in the annular portion 220 of the valve 20, which is then decoupled from the extractor which can now be removed from the tube T.

It should be noted that the described extractor and the characteristics of the valve 20 made so as to allow cooperation with operating members of the extruder constitute only a generic example, the use of extractors or other similar tools among those currently existing and used in operations being possible such as the laparoscopic ones or the like,

and on the valve corresponding elements to cooperate with these tools being provided.

CLAIMS

1. Permanent venous access device, for allowing the connection between an access vein and the skin, usable in particular in the dialysis treatments, essentially comprising:
   - a tube having the function of subcutaneous tunnel;
   - at least one graft end in a blood vessel with anchoring means such that said end is anchored to the wall of said vessel;
   - at least one valve, provided on said graft end, to be anchored on the access vein wall;
   - and the tube has an end outside of the body, which is provided with one valve or to which at least one valve
   - can be fastened, to be positioned outside of the skin;
   - possibly subcutaneous anchoring means to subcutaneously anchor the tube.
2. Device according to claim 1, characterized in that the valve (20) provided at the end of the tube (T) to be anchored to the vein is made so as to be removably fastened at said tube end, extractor means being provided in combination which can be removably coupled to said valve (20) and can be controlled from the outside of the tube, having control members positioned outside at the end of said tube (T) opposite to the anchoring end for the anchorage to the vein, which extractor means operate for decoupling and withdrawing the valve from the tube and therethrough and for replacing the valve (20) with a new valve (20) through said tube.

3. Device according to Claim 2, in which the tube anchoring end has a seat (10) removably housing the valve (20), the seat comprising seats (210) for the removable interlocking coupling of the valve (20), the seats cooperating with removable coupling members (120) of said valve.

4. Device according to one or more of the preceding claims, wherein the extractor comprises an elongate tubular body having an outside diameter of the order of magnitude of a catheter and which is suitable for passing through the tube and in which elongated body there are removable coupling members for the removable coupling with the valve body at the end of said elongated tubular body, the removable coupling members being able to be actuated by a control member provided at the outer or distal end of said elongate tubular body which is outside the tube so as to alternately take an engagement position, to radially engage by rotation with the valve body by fitting into a corresponding coupling seat provided in the valve body, and a disengagement position to disengage from said coupling seats in which the valve and extractor are released from each other.

5. Device according to claim 1 where the tube having the subcutaneous tunnel function has diameter tailored for the passage of at least one catheter, in particular of at least 12 French.

6. Device according to claim 1 or 2 where the valve at the end of the tube to be anchored on the vein wall is a diaphragm valve.

7. Device according to one or more of the preceding claims wherein at least one external skin anchoring element is further provided in order to permanently fasten the tube having the function of subcutaneous tunnel.

8. Device according to claim 7 where the external skin anchoring element is either of the adhesive "suture-less" anchoring type or is performed with stitches.

9. Device according to one or more of the preceding claims, wherein the valve to be positioned outside of the skin is provided embedded in an external fastening fitting that can be removably and sealingly connected to the ending length of the tube having the function of subcutaneous tunnel.

10. Device according to claim 9 where the external fastening fitting consists of a ring nut with a frusto-conical ending length and a threaded cylindrical length, which ring nut is fitted on the ending length of the tube and cooperates with a male fitting having a frusto-conical length cooperating with the frusto-conical length of the ring nut and a threaded length to screw said ring nut on said male fitting, the valve being positioned or embedded on the male fitting.

11. Device according to one or more of the preceding claims, wherein closing means to close the external end of the tube are provided, preferably the external fastening fitting has a free end to which a closing means, preferably a cap, can be removably and sealingly fastened.

12. Aid kit for the dialysis treatment, comprising at least:

- one venous access device according to one or more of claims 1 to 11;
- at least one disposable catheter, preferably a set of disposable catheters preferably with two lumina, having curves and lengths differing depending on the access site;

13. Kit according to claim 12 further comprising

- a venipuncture needle;
- a guide wire
- at least one dilator, preferably a dilator set;
- a peel away dilator.

14. Kit according to one or more of the preceding claims, characterized by comprising at least one or more valves (20) for replacing at least the valve (20) provided at the end of the tunneling coupling tube (T) to be coupled to the vein, at least one extractor tool (50) for the release from the tube (T) and the withdrawal of the valve (20) on its inner end and for inserting and locking in place a replacement valve (20) on said inner end of the tube, as well as a cap (P) of the tube end outside the skin, i.e. the distal end of the tube, which cap (P) either comprises a passageway able to be opened or is a replacement cap to replace a closing cap of said tube with said passageway for the elongated body of the withdrawal and replacement tool (50) for replacing and withdrawing the valve.

15. Kit according to Claim 14, characterized by comprising a narrowing device to narrow the tube length outside the skin and applicable so as to be detachable or so that it can be activated and deactivated.

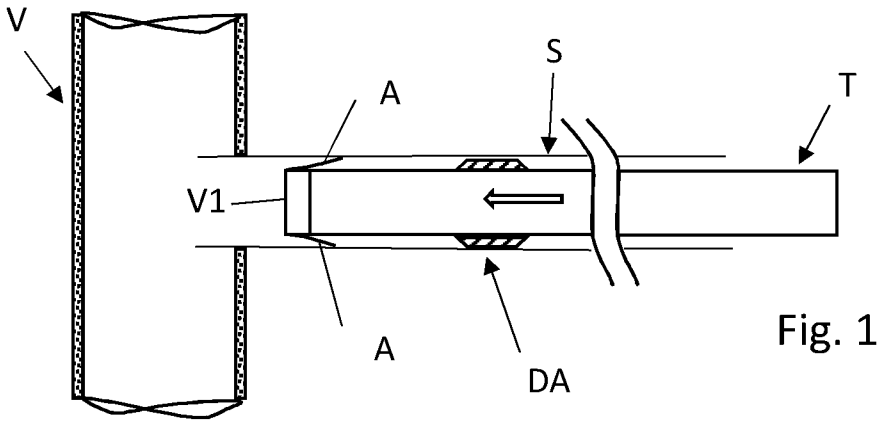


Fig. 1

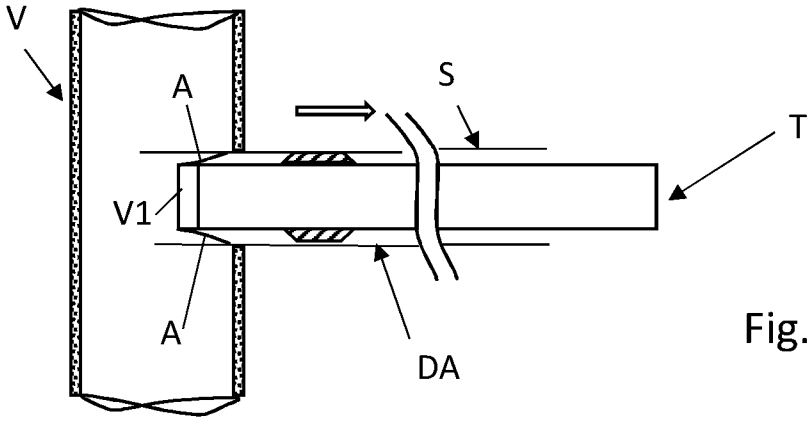


Fig. 2

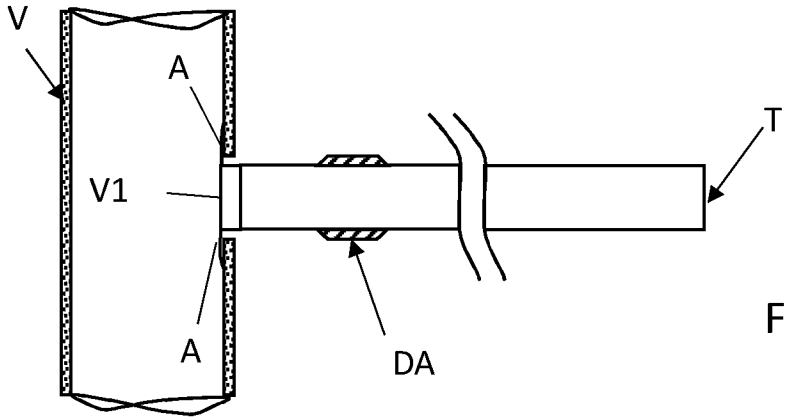


Fig. 3

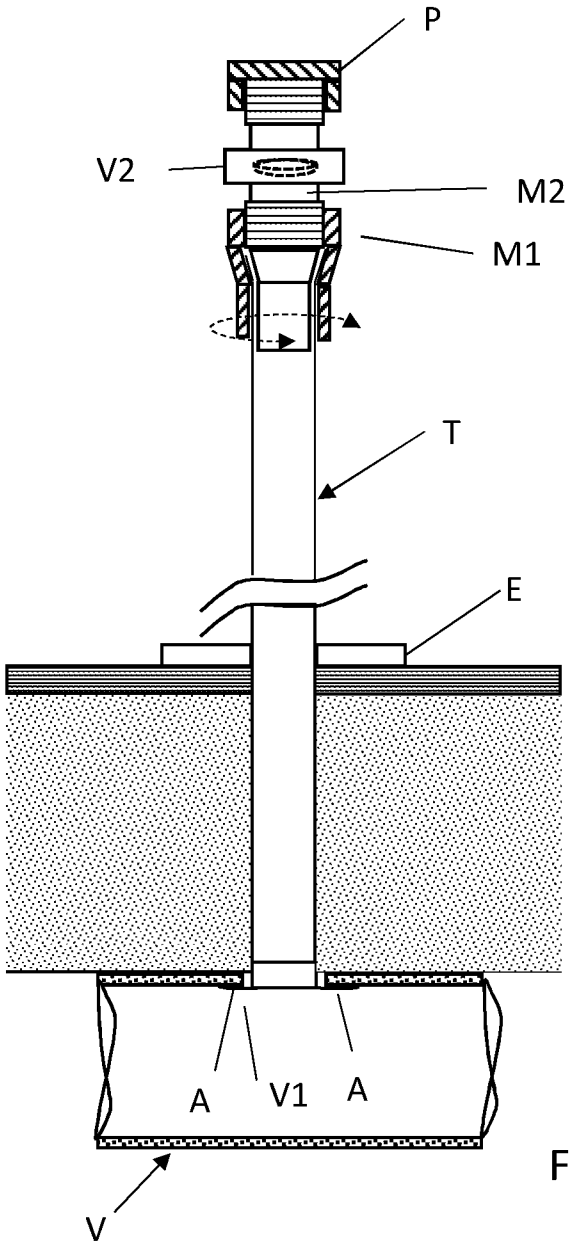


Fig. 4

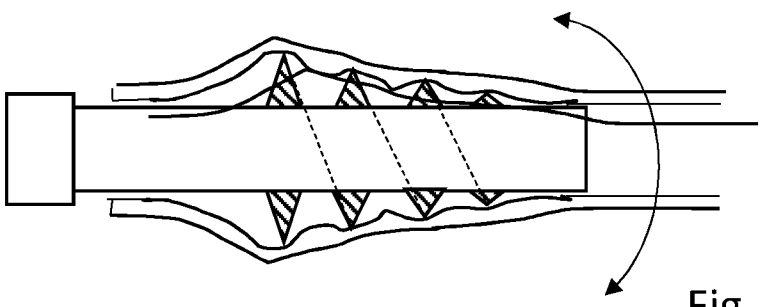


Fig. 5

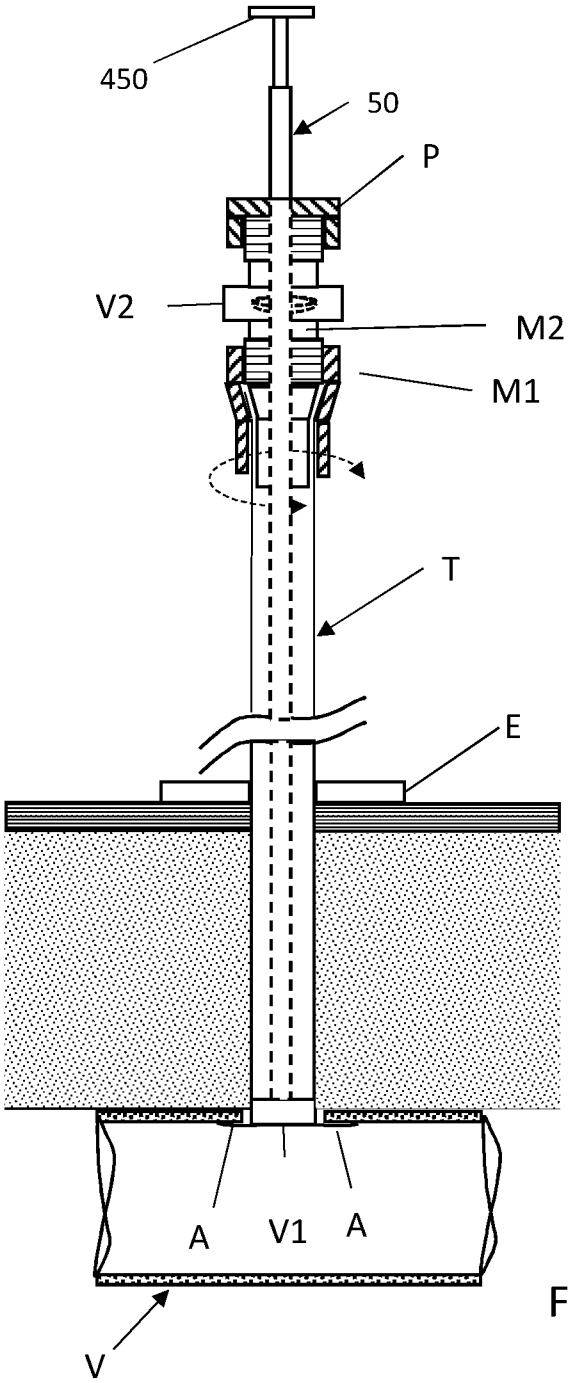
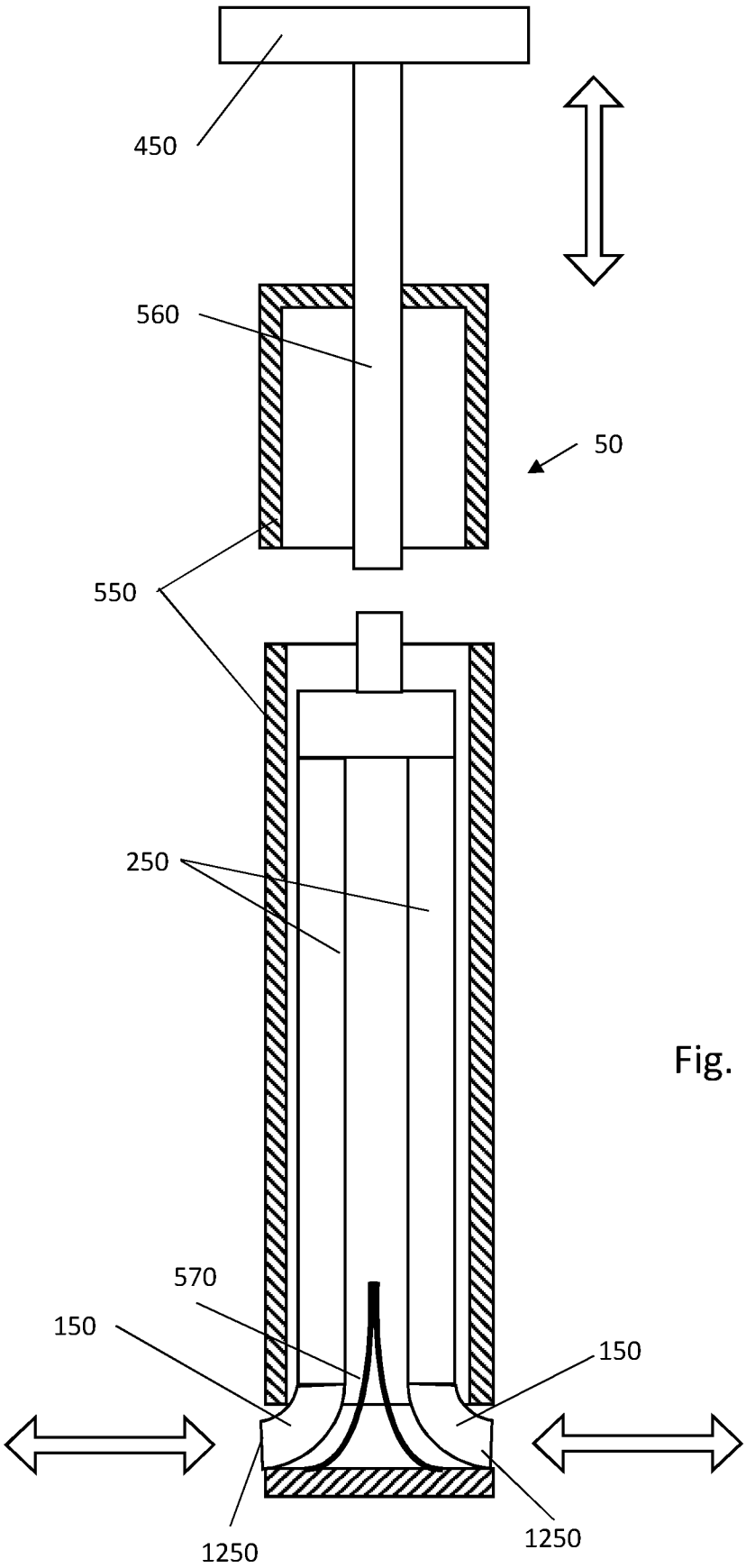


Fig. 6



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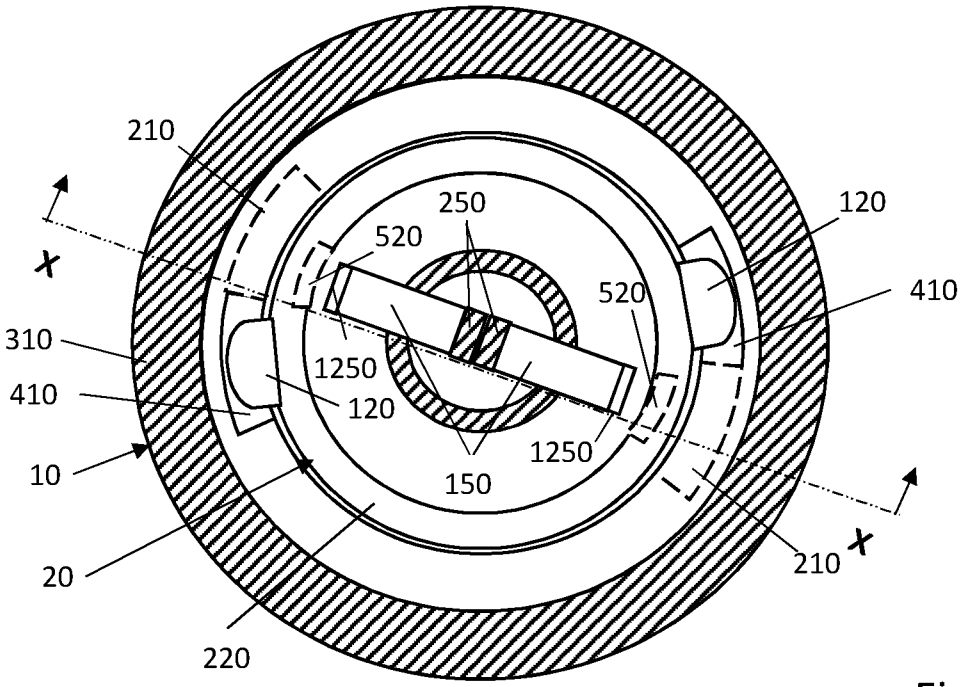
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Fig. 8

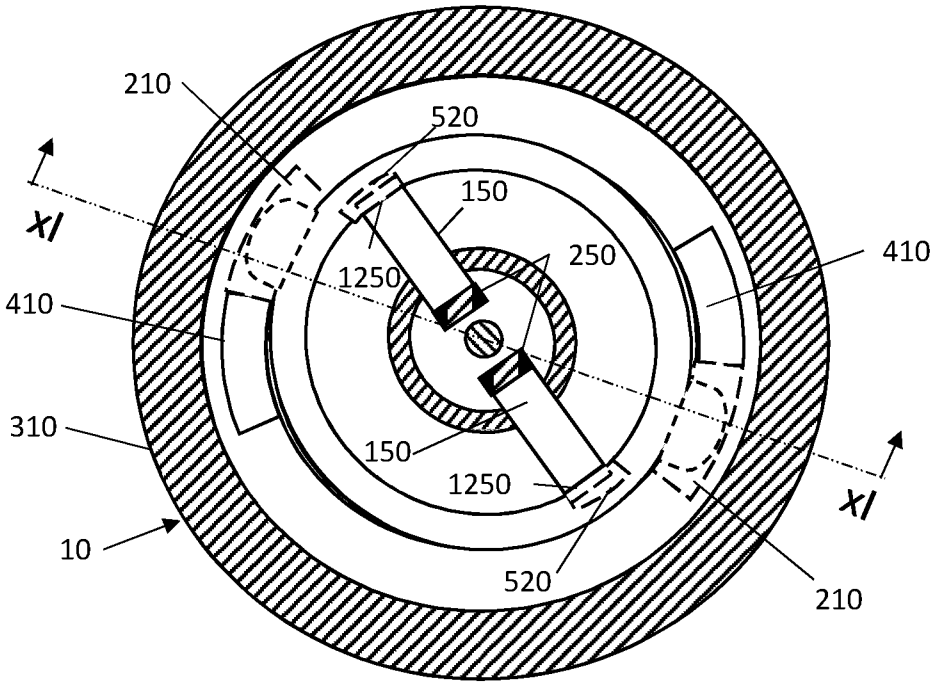
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Fig. 9

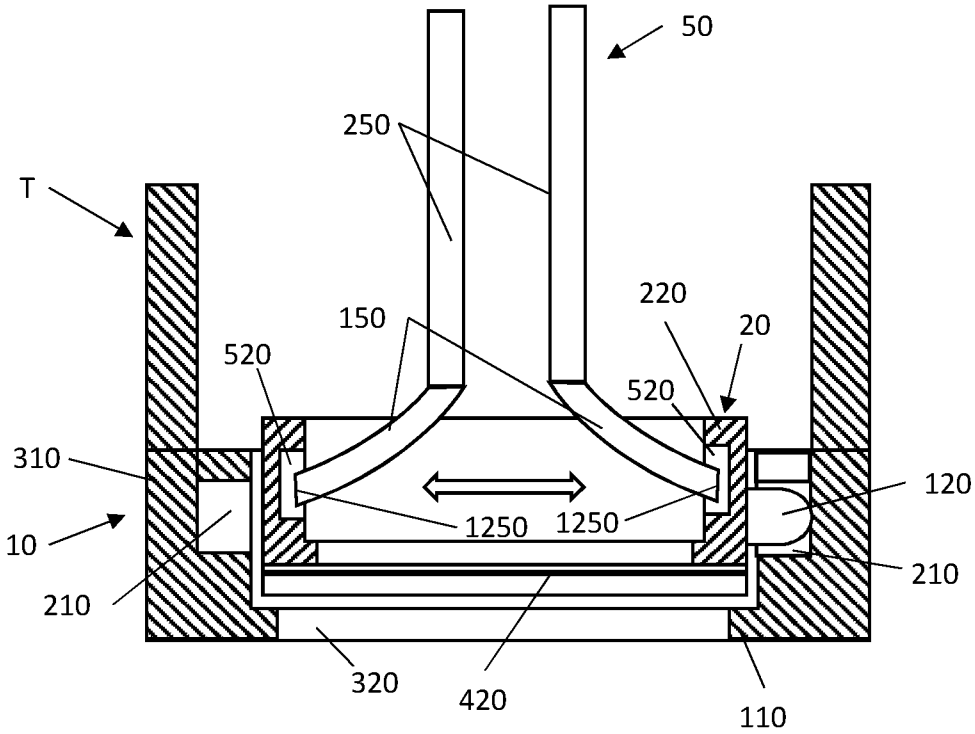
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Fig. 10

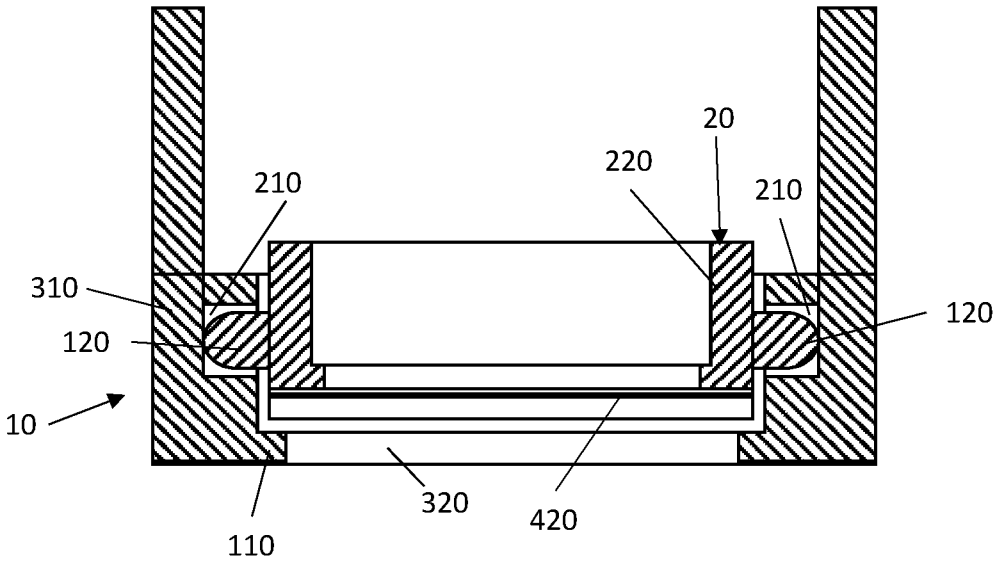
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Fig. 11

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2017/053081

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M39/02
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 A	WO 2013/049464 A2 (COVIDIEN LP [US]) 4 April 2013 (2013-04-04) the whole document	1,5-9, 11-13 2-4,10, 14,15

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

[X] See patent family annex.

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"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

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 August 2017	31/08/2017

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	Neiller, Frédéric

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INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2017/053081

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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Information on patent family members

International application No
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