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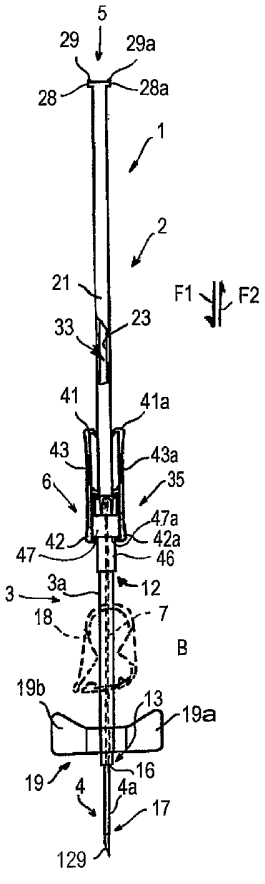
(54) Title: CANNULA DEVICE



(57) Abstract: A device (1) comprises needle means (7), cannula means (4) arranged for receiving in a removable manner inside thereof said needle means (7), casing means (2; 2a; 2b; 200) connected to said cannula means (4) and configured in such a way that said needle means (7) can be received in said casing means (2; 2a; 2b; 200).

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Cannula device

The present invention relates to a cannula device for withdrawing from and/or infusing into a patient biological fluids, in particular during haemodialysis, and for administering drugs in fluid form.

In the medical field, hollow-needle devices are known that are used in haemodialysis for withdrawing blood from patients and for subsequently reinfusing the treated blood into the latter. Such devices comprise a hollow needle associated with a flexible conduit, the free end of which is provided with a Luer-Lock joint. The hollow needle is arranged for being inserted into the body of the patient, in an anatomical region (normally the upper limb) of the latter hosting a vessel or fistula, previously implanted surgically. By means of the Luer-Lock joint, the flexible conduit can be connected to a tube by means of which the needle device, and therefore the body of the patient undergoing dialysis, is connected to the haemodialyzer.

In order to conduct the haemodialysis, an assigned operator, after closing the flexible conduit by means of a clamp with which the latter is provided, perforates the skin of the patient by means of the hollow needle, so as to reach and perforate the wall of the fistula. In this step, the operator handles the device by grasping a pair of flexible wings arranged near the hollow needle.

After positioning the hollow needle of the device, the operator can connect the flexible conduit to the tube coming from the haemodialyzator and thus act on the clamp to reopen the flexible conduit, thus connecting the latter to the patient. For the entire duration of the haemodialysis the hollow needle has therefore to remain inserted inside the body of the patient, from which it is extracted only at the end of treatment.

A clear drawback of the aforementioned hollow-needle devices consists of the fact that during the entire duration of the haemodialysis, i.e. for a few hours, the movements that the

patient undergoing the treatment can perform are significantly limited. This is necessary to prevent the rigid and pointed needle from producing muscular lesions and/or damaging the fistula following brusque movements of the patient, thus making a therapeutical treatment that is in itself unpleasant further uncomfortable.

Another drawback consists of the fact that when the needle is extracted from the body of the patient at the end of haemodialysis the operator is exposed to a significant risk of accident. In fact, the operator may prick himself with the needle contaminated by the blood of the patient, and this type of accident is particularly serious if the patient is affected by illnesses that are transmittable by blood.

Furthermore, to dispose of the used needle as waste, proper safety containers have to be used that have been designed for the purpose of minimising the risk of the aforementioned accidents when the needles are handled by the assigned operators.

This leads to substantial financial expenditure, as prescribed safety containers have to be purchased, and to substantial expenditure of time as the used needles first have to be collected in these containers and the latter then have to be disposed of as medical waste.

Also, in order to extract the hollow needle from the body of the treated patient, the operator has to handle a portion of the hollow needle arranged near to the anatomical region of the patient in which the hollow needle is inserted, which makes this operation significantly uncomfortable for the patient.

It should be observed that haemodialysis involves the use of a pair of hollow-needle devices connected to the haemodialyzer, one of which is used for withdrawing the blood from the patient and the other is used for returning to the latter the blood treated inside the haemodialyzer. Hollow needles are known to which a double external connection conduit is connected and which enable haemodialysis to be

conducted using a single device. These are, however, needles having a rigid structure and which therefore produce the aforementioned drawbacks.

An object of the invention is to improve the needle devices used for infusing and/or withdrawing biological fluids, in particular during haemodialysis, and for administering drugs in liquid form to a patient.

Another object is to provide a needle device usable in haemodialysis that avoids for a treated patient the significant discomfort caused in use by known needle devices.

A further object is to provide a needle device for infusing and/or withdrawing biological fluids and for administering drugs to a patient that prevents the risk for an assigned operator of accidentally pricking himself with the needle during use.

A further other object is to provide a needle device for infusing into a patient biological fluids and/or drugs that enable used needles to be disposed of in a substantially rapid and cheap manner.

Another further object is to provide a needle device that enables the use of a pair of rigid needle devices to be avoided for being able to withdraw blood from a patient and reinfuse the treated blood into the latter, as requested during execution of haemodialysis.

A still further object is to provide a needle device that reduces, in a patient undergoing haemodialysis, the discomfort due to the tasks that an operator has to perform near to a needle to extract the latter from the body of the patient.

Another still further object is to provide a method for conducting haemodialysis that can be carried out without leaving rigid needles inserted into the body of the patient during treatment.

In a first aspect of the invention, a device is provided, comprising needle means and cannula means arranged for removably receiving in the inside thereof said needle means,

characterised in that it furthermore comprises casing means connected to said cannula means and configured in such a way that said needle means can be received in said casing means.

Owing to this aspect, a device is made available that is usable for withdrawing and/or infusing fluids and is provided with needle means that can be retracted inside casing means.

In an embodiment, the casing means is made with a shape and dimensions that are such as to be able to completely contain the needle means inside the casing means.

In this way, a health worker, who has, for example, to reinfuse blood into a patient undergoing haemodialysis, can easily remove the needle from the body of the patient and leave in the withdrawing zone a flexible cannula, as occurs when known cannula needles are used. Unlike the latter, however, the operator is no longer exposed to the risk of accidental pricks, inasmuch as the needle, being protected by casing means, cannot come into contact with the body of the operator during use of the device.

Furthermore, once use of the latter has terminated, the casing means effectively acts as a protective casing for the respective needle, which can thus be directly disposed of as medical waste without having been first stored in safety containers.

In an embodiment, the casing means is made of rigid material.

In another embodiment, the casing means is made of flexible material and may extend over an appropriate length. This enables the operator to handle the needle means keeping at a certain distance from the body of the patient, so as to reduce the discomfort caused to the latter when the needle means is removed from the respective cannula means inserted into the body of the patient.

In a further embodiment, the device is provided with locking means that prevents the needle from accidentally exiting from the casing means and thus makes the device provided by the invention significantly safe.

In a still further embodiment, the locking means is shaped in such a way as to be able to lock the needle means even in a position in which the latter protrudes outside the free end of the cannula means, as required when the operator has to perforate the skin of the patient. In this way, the needle means is prevented from accidentally retracting inside the cannula means before it has reached a desired depth in the body of the patient.

In a second aspect of the invention, grip means is provided, arranged for being coaxially associated with needle means comprised in a device for withdrawing and/or infusing fluids and comprising a hollow body interposed between flexible wing portions fixed on opposite sides of said hollow body, characterised in that said wing portions are connected together by a flexible connecting portion, shaped in such a way as to be able to surround at least partially a portion of said device.

Owing to this aspect, a butterfly grip is provided that enables an operator to handle a withdrawing and/or infusing device more effectively and safely. In fact, unlike known butterfly grips, which enable only the portion of device comprising the needle to be handled directly, the grip means provided by the invention enables movements of the device to be controlled by simultaneously acting on several portions of the latter.

In an embodiment, in the flexible connecting portion channel means is obtained, arranged to receive an adjacent portion of conduit means comprised in the withdrawing and/or infusing device.

In a third aspect of the invention, cannula means is provided, arranged for penetrating an anatomical region and for being traversed by a fluid substance, characterised in that it comprises first transit conduit means and second transit conduit means shaped in such a way as to enable said cannula means to withdraw said fluid substance from said region through said first transit conduit means and infuse

into said region said fluid substance by means of said second transit means, or vice versa.

Owing to this aspect, cannula means is available, associable with a single needle, that enables blood to be withdrawn from and simultaneously reinfused into the same patient, as required for example during haemodialysis, thereby avoiding the insertion of a pair of needles into the body of the same patient.

In a fourth aspect of the invention, a method is provided for conducting haemodialysis in a patient, comprising:

-inserting needle means into a portion of the vascular apparatus of said patient, said needle means being arranged inside cannula means;

-slidably removing said needle means from said cannula means, leaving said cannula means inserted in said portion;

-connecting said patient, through said cannula means, to an apparatus for haemodialysis.

In an embodiment, inserting the needle means into casing means is provided, said casing means being connected to the cannula means and arranged for keeping the needle means separate from the external environment.

Owing to this aspect, a method is available for conducting haemodialysis that can be conducted without maintaining rigid needles inserted in the body of the patient for the entire duration of the treatment.

The invention can be better understood and implemented with reference to the enclosed drawings, which illustrate some exemplifying and non-limitative embodiments thereof, in which:

Figure 1 is a longitudinal partially sectioned view of a cannula-needle device provided with casing means and locking means, shown in an operating position;

Figure 2 is a view like the one in Figure 1, showing the device in a rest position;

Figure 3 is a fragmentary and incomplete longitudinal section of a detail of Figure 2;

Figure 4 is a longitudinal view of a portion of the casing means of the device in Figure 1;

Figure 5 is a further longitudinal view of the portion of the casing means shown in Figure 4;

Figure 6 is an enlarged longitudinal view of locking means comprised in the device in Figure 1;

Figure 7 is a perspective view of the locking means shown in Figure 6;

Figure 8 is an enlarged fragmentary and incomplete longitudinal section of cannula means comprised in the device in Figure 1;

Figure 9 is a fragmentary and incomplete longitudinal view of needle means comprised in the device in Figure 1;

Figure 10 is a perspective view of an embodiment of the locking means in Figure 6;

Figure 11 is an enlarged, fragmentary and incomplete perspective view showing the operation of the locking means in Figure 10;

Figure 12 is an enlarged, fragmentary and incomplete longitudinal view showing the device of Figure 1 provided with an embodiment of the casing means;

Figure 13 is an enlarged fragmentary and incomplete perspective view showing an operating step of another embodiment of the casing means of the device in Figure 1;

Figure 14 is an enlarged, fragmentary, incomplete and partially sectioned view of a further operating step of another embodiment of the casing means shown in Figure 13;

Figure 15 an enlarged fragmentary and incomplete perspective view showing an operating step of a further embodiment of the casing means of the device in Figure 1;

Figure 16 is a fragmentary longitudinal view of another operating step of the further embodiment of the casing means shown in Figure 15;

Figure 17 is an enlarged perspective view showing grip means that is associable with a device for withdrawing and/or infusing fluids;

Figure 18 is an enlarged longitudinal section of a cannula-needle device provided with casing means and devoid of locking means, shown in a rest position;

Figure 19 is an enlarged, fragmentary and incomplete detail of the section in Figure 18;

Figure 20 is a view like the one in Figure 18, showing the device in an operating position;

Figure 21 is an enlarged, fragmentary and incomplete detail of the section in Figure 20;

Figure 22 is an incomplete, fragmentary and partially sectioned longitudinal view showing an automatically drivable embodiment of the device in Figure 18 in a rest position;

Figure 23 is a view like the one in Figure 22, showing the device in an operating position;

Figure 24 is an enlarged longitudinal section, showing two-way cannula means;

Figure 25 is an enlarged and fragmentary longitudinal section showing the two-way cannula means associated with a device like the one in Figure 18;

Figure 26 is a fragmentary and incomplete perspective view of another embodiment of the device in Figure 18;

Figure 27 is a further perspective, fragmentary and incomplete view of the device shown in Figure 18;

Figure 28 is a longitudinal view of a component of the device in Figure 22;

Figure 29 is a fragmentary and incomplete perspective view of a further embodiment of the device in Figure 18;

Figure 30 is a view like the one in Figure 29, showing a component of the device in Figure 29.

With reference to Figures 1 to 7, a cannula-needle device 1 comprises, in sequence, a flexible casing portion 2, a conduit portion 3 and a cannula portion 4, that are mutually aligned.

The flexible casing portion 2, made, for example, of polypropylene, has a proximal end 5, in use facing an operator, and a distal end 6, opposite the proximal end 5.

The flexible casing portion 2 is formed by a pair of slat elements 21, 22 connected to each other and arranged parallel to a longitudinal axis, that is not shown, of the device 1. In each slat element 21, 22, which has a cross section that is approximately shaped as a half-ring, a longitudinal channel 23 is obtained. Each longitudinal channel 23 is interposed between a closing portion 24, corresponding, in use, to the proximal end 5 of the device 1, and a connection portion 25. Each closing portion 24, substantially shaped as a half-cylinder, has a contact face 24a in which a pair of recesses 26, 26a and a pair of appendages 27, 27a are obtained that are alongside each other. The pairs of recesses 26, 26a and the pairs of appendages 27, 27a are arranged on the contact faces 24a of the two slat elements 21, 22 in such a way that, during assembly of the flexible casing portion 2, each of the appendages 27, 27a of the contact face 24a of the slat element 21 engages a corresponding recess 26, 26a of the contact face 24a of the slat element 22. Similarly, each of the appendages 27, 27a of the contact face 24a of the slat element 22 engages one of the recesses 26, 26a of the contact face 24a of the slat element 21. At an end of each closing portion 24 opposite the longitudinal channel 23 there is a pair of lateral protrusions 28, 28a, each of which is arranged orthogonally to the closing portion 24 and is provided with a respective locking appendage 29, 29a. In an end of each closing portion 24 adjacent to the longitudinal channel 23 and opposite the pair of lateral protrusions 28, 28a an abutment surface 30 is obtained that is substantially semicircle-shaped.

Each connection portion 25 is approximately shaped as a hollow half-cone, and comprises a proximal portion 25a and a distal portion 25b, which are connected together. The proximal portion 25a, adjacent to the longitudinal channel 23, is approximately shaped as a half-ring and comprises an abutment zone 25c, facing the longitudinal channel 23. The distal portion 25b is substantially shaped as a hollow half-

cylinder, in such a way that when the slat elements 21 and 22 are associated with one another and form the flexible casing portion 2, the respective reciprocally juxtaposed distal portions 25b form a male Luer connection of known type.

In an embodiment that is not shown, inside each distal portion 25b a protruding element is obtained that is shaped as a half-ring. When the flexible casing portion 2 is assembled, the two reciprocally juxtaposed half-rings form a seal ring.

Between the proximal portion 25a and the distal portion 25b a further recess 31 and a further appendage 32 are interposed that face each other. The further recess 31 and the further appendage 32 of each connection portion 25 are arranged in such a way that, during assembly of the flexible casing portion 2, each further appendage 32 engages a corresponding further recess 31.

When the flexible casing portion 2 is assembled, the closing portions 24 and the connection portions 25 of the two slat elements 21, 22 are reciprocally juxtaposed, whilst the remaining portions of the slat elements 21 and 22, comprising the respective longitudinal channels 23, are spaced apart from each other. In this way, between the two longitudinal channels 23 a longitudinal slot 33 is formed, the length of which substantially corresponds to the length of each longitudinal channel 23 and the width of which corresponds to the width of each slat element 21, 22.

When the device 1 is in a rest configuration A, in the longitudinal slot 33 of the flexible casing portion 2 a cylindrical steel needle 7 is completely contained that is provided with a proximal end 8 and with a pointed end 129. During use, the proximal end 8 faces the proximal end of the flexible casing portion 2 and is associated with a locking element 35. The pointed end 129 is opposite the proximal end 8 and is cut obliquely to a longitudinal axis, not shown, of the needle 7.

In an embodiment which is not shown, the needle 7 is provided with a pointed end cut in such a way as to approximately form a three-face pyramid. This embodiment makes the penetration of the needle 7 less painful for the patient and makes the device 1 easier for the operator to use as he does not need to orientate the device 1 in such a way as to place the pointed end in a suitable position for effectively perforating the skin of the patient.

The locking element 35 comprises a cylinder-shaped cursor portion 36 in opposite ends of which a seat 34 and an abutment face 36a are obtained. In the seat 34, facing the distal end 6 of the flexible casing portion 2, the proximal end 8 of the needle 7 is inserted. The abutment face 36a is circular and faces the proximal end 5 of the flexible casing 2. The cursor portion 36 is received, in use, in the longitudinal channels 23 delimiting the longitudinal slot 33, and is interposed between two grip portions 37 and 38, having the same shape and being positioned in use outside the longitudinal slot 33. The cursor portion 36 is connected to the two grip portions 37 and 38 by means of a pair of arched portions 39, 40, having the same shape. Each of the arched portions 39, 40 is flexible and extends from the abutment portion 36, near to the seat 34, to a respective connecting face 37a, 38a of the corresponding foldable casing 2a grip portion 37, 38, facing the abutment portion 36.

Each grip portion 37, 38 furthermore comprises a proximal hooking portion 41, 41a facing the closing portion 24, and a distal hooking portion 42, 42a, facing in the direction of the connection portion 25.

Each proximal hooking portion 41, 41a, comprises a hook portion 44, 44a, arranged for engaging, in use, the respective locking appendage 29, 29a. Each distal hooking portion 42, 42a is provided with a hook appendage 45, 45a.

In each grip portion 37, 38 a notched zone 43, 43a is obtained that is arranged for ensuring an operator a more secure grip of the lock element 35. Each notched zone 43, 43a

is obtained on a face of each grip portion 37, 38 opposite the respective connecting face 37a, 38a, and is arranged near to the respective proximal hooking portion 41, 41a.

The conduit portion 3 is flexible and cylindrically shaped and made, for example, of soft PVC. The conduit portion 3 is delimited by a side wall 3a and comprises a further proximal end 12, which is associated, in use, with the distal end 6 of the flexible casing portion 2 by means of a female Luer connection 46 of known type, and a further distal end 13, opposite the further proximal end 12 and associated, in use with the cannula portion 4. Into the female Luer connection 46 the male Luer connection is inserted consisting of the reciprocally juxtaposed distal portions 25b of the connection portions 25 of the two slat elements 21, 22. Between the male Luer connection formed by the distal portions 25b and the female Luer connection 46 a seal 15 is interposed that is made of a suitably resilient material and is substantially disk-shaped.

In order to enable the flexible casing portion 2 and the conduit portion 3 to remain associated with each other during use, a ring nut element 47 is provided, a proximal end of which is fitted on the distal end 6 of the flexible casing portion 2. Inside a distal end of the ring nut element 47 an internal thread (that is not shown) is obtained, which is engaged, in use, by a corresponding thread (that is not shown) with which the female Luer connection 46 is provided. In this way, the flexible casing portion 2 and the conduit portion 3 remain connected to each other until the operator acts by loosening the casing portion 2 from the conduit portion 3.

The cannula portion 4 is flexible and shaped as a cylindrical tube, made, for example, of polyurethane. The cannula portion 4 has a cross section the diameter of which is less than that of the cross section of the conduit portion 3 and comprises a fixed end 16, that, in use, is fixed to the further distal end 13 of the conduit portion 3, and a free end 17, opposite

the fixed end 16. From the fixed end 17, in use, a portion of the needle 7 comprising the pointed end 129 may protrude.

In an embodiment that is not shown, a protection element of the cannula portion 4 is provided, which is shaped as a cylindrical tube and made of plastics. The protection element encloses the cannula portion 4 and the pointed end 129 of the needle 7, protruding outside the distal end 17, and has to be removed before use.

The device 1 furthermore comprises a clamp 18 of known type (that is shown by a dotted line), made, for example, of polypropylene, and a butterfly element 19, of known type, comprising a pair of flexible wings 19a and 19b and made, for example, of soft PVC. The butterfly element 19 surrounds, in use, the conduit portion 3 near to the further distal end 13 of the latter, whilst the clamp 18 is located, in use, along the conduit portion 3, between the further proximal end 12 of the latter and the butterfly element 19.

With reference to Figure 8, on a side wall 4a of the cannula portion 4, near to the free end 17 of the latter, a plurality of through holes 60 is obtained. The latter are arranged orthogonally to a longitudinal axis, that is not shown, of the cannula portion 4 opposite one another. The through holes 60 act as supplementary inlet paths for a biological fluid, for example blood, withdrawn from a patient by means of the cannula portion 4. In this way, the through holes 60 enable the volume of fluid to be increased that penetrates the cannula portion 4 during the withdrawal and thus make the device 1 more effective.

In an embodiment which is not shown, the through holes 60 are reciprocally staggered along the side wall 4a of the cannula portion 4.

In use, in order to withdraw blood from a patient during haemodialysis by means of the device 1, an operator first takes the device 1 from the rest configuration A to an operating configuration B.

In the rest configuration A (Figure 2), the needle 7 is completely contained in the longitudinal slot 33 of the flexible casing portion 2, and is kept locked in this position due to the hook portions 44, 44a, each of which engages the respective locking appendage 29, 29a, thus preventing the cursor portion 36, and therefore the needle 7, from sliding along the longitudinal slot 33.

The operator can exert pressure on the distal hooking portions 42, 42a in two opposite directions indicated by the arrows F3 and F4, both orthogonal to the flexible casing portion 2, in such a way as to move the distal hooking portions 42, 42a near the flexible casing portion 2. Owing to the flexibility of the connecting portions 39 and 40 and as a result of the aforementioned pressure, the two proximal hooking portions 41 41a are removed from the proximal end 5 of the flexible casing portion 2 in two directions indicated by the arrows F5 and F6, opposite each other and orthogonal to the casing portion 2. In this way, the hook portions 44, 44a disengage the locking appendages 29, 29a, and the operator, by acting on the locking portion 35, can slide the cursor portion 36, and therefore the needle 7, along the longitudinal slot 33, in a direction indicated by the arrow F1, parallel to the casing portion 2.

Consequently, the needle 7 can exit from the flexible casing portion 2 through the male Luer connection formed by the two distal portions 25b, traverse the female Luer connection 46, the conduit portion 3 and the subsequent cannula portion 4 until the pointed end 129 is made to protrude from the free end 17. The stroke of the cursor portion 36 terminates near to the two reciprocally juxtaposed abutment zones 25c, against which the arched portions 39 and 40 stop. When the locking element 35 reaches this position, the distal hooking portions 42, 42a are near to a distal free edge 47a of the ring nut element 47, that is engaged by the hook appendages 45, 45a. In this way, the needle 7 is locked in such a way as not to be able to accidentally enter inside the flexible

casing portion 2 and the device 1 is in the operating configuration B (Figure 1).

Alternatively, the device 1 can be provided by the manufacturer already set up in the operating configuration B, thus being ready to be used by the operator.

Once the device 1 is in the operating configuration B, the operator, by grasping and clamping together the wings 19a, 19b of the butterfly element 19, can direct the needle 7, inserted into the cannula portion 4, to a preset anatomical region of the patient.

Then, after perforating the skin of the patient until the fistula at which to start the haemodialysis treatment is reached, the operator acts on the locking element 35 by simultaneously pressing the distal hooking portions 41, 41a so as to move the latter to the casing portion 2 in the two directions F3 and F4. In this way, owing to the flexibility of the arched portions 39 and 40, the distal hooking portions 42, 42a are removed by the ring nut element 47 in the two directions F5 and F6 and the respective hook appendages 45, 45a disengage the distal free edge 47a. Once the needle 7 is unlocked, the latter can be extracted from the skin of the patient by the operator, who by acting on the locking element 35, slides the needle 7 in a direction indicated by the arrow F2, parallel to and opposite the direction F1. The needle 7 is thus returned through the cannula portion 4 (which remains inside the body of the patient) and through the conduit portion 3, inside the flexible casing portion 2. The stroke of the cursor portion 36 in the direction F2 ends near to the reciprocally juxtaposed abutment surfaces 30 of the closing portions 24, against which the abutment face 36a of the cursor portion 36 stops. The needle 7 remains locked inside the flexible casing portion 2 owing to the action disclosed above of the proximal hooking portions 41 and 41a of the locking element 35.

If a volume of blood coming from the patient through the cannula portion 4 penetrates the conduit portion 3, the seal

15 prevents this volume from exiting from the conduit portion 3 when the needle 7 is extracted from the seal 15 and is relocated inside the flexible casing portion 2. This is possible because in the seal 15 made of resilient material the orifice (that is not shown) that is produced there by the pointed end 129 closes once the needle 7 has been extracted. The seal ring, formed by the two half-rings obtained inside the distal portions 25b, cooperates with the seal 15 in preventing the aforementioned volume of blood from penetrating the flexible casing portion 2.

At this point, the operator can close the conduit portion 3 by acting on the clamp 18 and remove the flexible casing portion 2 from the conduit portion 3, by loosening the ring nut element 47 from the female Luer connection 46 and simultaneously extracting from the latter the male Luer connection formed by the distal portions 25b of the connection portion 25.

After removing the flexible casing portion 2, the operator can thus, by means of the female Luer connection 46, connect the conduit portion 2 to a tube (that is not shown) that conveys the blood of the patient to a haemodialyzer (that is not shown).

Once the needle 7, which has been used for the withdrawal and is thus contaminated by the blood of the patient, has again been positioned inside the flexible casing portion 2, the pointed end 129 is no longer in contact with the external environment. This prevents the operator from accidentally pricking himself with the pointed end 129, thereby risking infection with pathogenic agents that may be present in the blood of the patient. The flexible casing portion 2 may furthermore be immediately eliminated as medical waste inasmuch as it is no longer necessary to store the needle 7 in a security container to be subsequently disposed of as medical waste as the needle 7 is protected by a casing.

With reference to Figure 9, an embodiment of the needle 7 is provided that is equipped with a longitudinal notch 48. The

length of the longitudinal notch 48 is such that the latter extends in use from a zone of the cannula portion 4 located upstream of the free end 17 of the latter to a zone of the conduit portion 3 located downstream of the butterfly element 19. In use, as the longitudinal notch 48 is adjacent to the through holes 60 obtained in the cannula portion 4, when the needle 7 reaches and perforates a blood vessel the blood penetrates, through the through holes 60, occupying a space comprised between the side wall 4a of the cannula portion 4, the side wall 3a of the conduit portion 3 and the longitudinal notch 48. In this way, as the conduit portion 3 is located completely outside the body of the patient and is therefore well visible to the operator, the latter can check that he has positioned the needle 7 correctly owing to the presence of blood in the conduit portion 3, downstream of the butterfly element 19.

With reference to Figure 10, an embodiment of the locking element 35 is provided that is equipped with a pair of pair of guiding elements 49, 50. Each, substantially "C"-shaped, guiding element 49, 50 is inserted into the thickness of the respective distal hooking portion 41, 41a and is arranged transversely to the latter, so as to turn its concavity towards the longitudinal slot 33. Each guiding element 49, 50, in use, transversely embraces both slat elements 21, 22 of the flexible casing portion 2, thus guiding sliding of the locking element 35 and keeping the slat elements 21, 22 correctly alongside one another.

With reference to Figure 12, an embodiment of the device 1 is provided in which the flexible casing portion 2 is provided with a coaxial tubular element 51, having a cross section the diameter of which is greater than that of the flexible casing portion 2. The tubular element 51 comprises a closed proximal end 51a, inside which the proximal end 8 of the needle 7 is fixed, and an open distal end 51b, opposite the closed proximal end 51a and comprising the locing element 35, without the cursor portion 36. The open distal end 51b

comprises locking means, not shown, that prevents the tubular element 51 from being accidentally separated from the flexible casing portion 2 during use. In the proximal end 5 of the flexible casing portion 2 a through hole is obtained, which is not shown, that enables the needle 7 to be simultaneously received in the longitudinal slot 33 and inside the tubular element 51.

When an operator, by acting on the locking element 35, slides the tubular element 51 in the direction F1 the flexible casing portion 2 is enclosed inside the latter whereas the needle 7 exits from the flexible casing portion 2, traverses the conduit portion 3 and partially protrudes outside the cannula portion 4. When the operator, by again acting on the locking element 35, slides the tubular element 51 in the direction F2, the flexible casing portion 2 exits from the latter and the needle 7 is returned completely inside the device 1, being lodged partially in the flexible casing portion 2 and partially in the tubular element 51.

With reference to Figures 13 and 14, an embodiment of the device 1 is provided comprising a foldable casing 2a. The foldable casing 2a comprises a bellows wall 61, delimiting a cavity 64 in which, in use, the needle 7 is received. A distal end 63 of the bellows wall 61 comprises a male Luer connection, that is not shown, and in a proximal end 62 of the bellows wall 61, opposite the distal end 63 and closed, the seat 34 is obtained that is intended to receive the proximal end 8 of the needle 7. The foldable casing 2a comprises a further locking element 35a that is devoid of the proximal hooking portions 41, 41a and of the cursor portion 36. In the further locking element 35a the arched portions 39, 40 are fixed to the bellows wall 61, at the proximal end 62 of the latter. In use, when an operator moves the further locking element 35a in the direction F1, the bellows wall 61 contracts, significantly reducing the length of the foldable casing 2a and taking the needle 7 out of the latter. Subsequently, when the operator moves the further locking

element 35a in the direction F2, the bellows wall 61 expands longitudinally, the foldable casing 2a returns to the initial length thereof and the needle 7 is received inside the foldable casing 2a.

With reference to Figures 15 and 16, an embodiment of the device 1 is provided comprising a telescopic casing 2b. The telescopic casing 2b comprises a first tubular portion 65, a second tubular portion 66 and a third tubular portion 67, that are reciprocally coaxial and have a cross section the diameter of which decreases progressively from the first tubular portion 65 to the third tubular portion 67. A distal end 65b of the first tubular portion 65, adjacent, in use, to the ring nut element 47 comprises a male Luer connection (not shown). A disc element 68 is fixed to a proximal end 67b of the third tubular portion 67, opposite the distal end 65b of the first tubular portion 65, and to an internal face, which is not shown, of the disc element 68, the proximal end 8 of the needle 7 is fixed. In the first tubular portion 65 and in the second tubular portion 66 there are respectively obtained a first window 65a and a second window 66a, arranged for receiving projecting means, not shown. The latter protrude respectively from corresponding end portions of the second tubular portion 66 and third tubular portion 67. The projecting means, in use, limit the maximum sliding extent of the second tubular portion 66 in relation to the first tubular portion 65 and limit the maximum sliding extent of the third tubular portion 67 in relation to the second tubular portion 66. When an operator exerts pressure on the disc element 68 in the direction F1, the third telescopic portion 67 is received in the second tubular portion 66, and the latter is in turn received in the first tubular portion 65. In this way the telescopic casing 2b closes again and assumes a configuration (Figure 16) in which only the first tubular portion 65 is visible externally. In this configuration, the needle 7 is contained only partially in the telescopic casing 2b and the pointed end 129 protrudes

outside the cannula portion 4. Subsequently, when the operator grasps the disc element 68 and draws it to himself, i.e. in the direction F2, the third tubular portion 67 is extracted from the second tubular portion 66, and the latter is extracted from the first tubular portion 65. In this way, the telescopic casing 2b opens and the needle 7 is enclosed completely in the latter. The projecting means, by enabling the operator to lock the third tubular portion 67 in an extracted position in relation to the second tubular portion 66 and to lock the second tubular portion 66 in an extracted position in relation to the first tubular portion 65, acts as a locking means, thus performing a function that is similar to that performed by the locking element 35 disclosed above.

In an embodiment, which is not shown, a device is provided 1 having a telescopic casing comprising two tubular portions.

In an other embodiment, which is not shown, a device 1 is provided having a telescopic casing comprising four or more tubular portions.

In a further embodiment, which is not shown, a device 1 is provided having a telescopic casing in which, with one of the coaxial tubular portions, an embodiment of the locking element 35 is provided that is devoid of the cursor portion 36.

Parts of the device in Figures 18 to 21 common to parts already disclosed in relation to the device in Figures 1 to 5 are indicated by the same reference numbers.

With reference to Figures 18 to 21, an embodiment of the cannula-needle device 1 devoid of locking means is provided and comprising, in sequence, the casing portion 2, the conduit portion 3 and the flexible cannula portion 4, that are aligned on one another. The casing portion 2 is shaped as a rigid hollow cylinder, having a proximal end 5, facing an operator during use, and a distal end 6, opposite the proximal end 5. When the device 1 is in a rest configuration A, in the casing portion 2 a cylindrical needle 7, made of steel, is contained completely, said needle 7 being provided

with a proximal end 8, facing, in use, the operator, and with a pointed end 129, opposite the proximal end 8 and cut obliquely in relation to a longitudinal axis, not shown, of the needle 7. With the proximal end 8 a cursor 9 is associable, that is graspable by the operator and protruding from a longitudinal groove 10 obtained along the casing portion 2. By sliding the cursor 9 along the longitudinal groove 10 in a direction F1 parallel to the casing portion 2 and opposite the proximal end 5 of the latter, the needle 7 can exit almost completely from the casing portion 2.

The conduit portion 3, shaped as a flexible cylindrical tube, has a further proximal end 12, which is associated, in use, with the distal end 6 of the casing portion 2 by a Luer-Lock joint 20 of known type, and a further distal end 13, which is opposite the further proximal end 12 and associated, in use, with the cannula portion 4. The Luer-Lock joint comprises a Luer cap 11 , to which the distal end 6 of the casing portion 2 is fixed, and a Luer connection 14, interposed between the cap portion 11 and the further proximal end 12 of the conduit portion 3. Between the cap portion 11 and the adjacent connection portion 14, which are reciprocally associated, a seal 15 is interposed, that is made of a suitably resilient material and is substantially disk-shaped.

The flexible cannula portion 4 is shaped as a hollow cylinder, having a cross section the diameter of which is less than that of the cross section of the conduit portion 3, and is provided with a fixed end 16, which, in use, is fixed to the further distal end 13 of the conduit portion 3. Opposite the fixed end 16 there is a free end 17, from which, in use, a portion of the needle 7 may protrude, comprising the pointed end 129.

The device 1 is completed by a clamp 18 and by a butterfly element 19 comprising a pair of flexible wings 19a and 19b, of known type and shown by means of a dotted line. The butterfly element 19 surrounds, in use, the conduit portion 3 near to the further distal end 13 of the latter, while the

clamp 18 is located, along the conduit portion 3, between the further proximal end 12 of the latter and the butterfly element 19.

In use, the operator who intends to use the device 1 for withdrawing blood from a patient, which is not shown, during haemodialysis, can grasp the cursor 9, sliding it in the direction F1 along the longitudinal groove 10. In this way, the needle 7 exits from the casing portion 2, travels along the entire conduit portion 3, traverses the Luer-Lock joint 20 and runs along the subsequent cannula portion 4 until the pointed end 129 protrudes from the free end 17. In this way, the device 1 goes from the rest configuration A to an operating configuration B. Alternatively, the device 1 can be provided by the manufacturer already set up in the operating configuration B, thus being ready to be used by the operator. Once the device 1 is in the operating configuration B, the operator, by grasping and reciprocally clamping the wings 19a, 19b of the butterfly element 19, can then move the needle 7, covered by the cannula portion 4 and direct it to an anatomical region, which is not shown, of the patient. Subsequently, after perforating the skin of the patient until reaching the fistula from which to start the haemodialysis treatment, the operator, by moving the cursor 9 in a direction F2 parallel to and opposite the direction F1, can extract the needle 7 from the skin of the patient, returning the needle 7 inside the casing portion 2, through the cannula portion 4 (which remains inside the body of the patient) and thus through the conduit portion 3.

At this point, the operator can close the conduit portion 3 by acting on the clamp 18 and remove the casing portion 2 from the conduit portion 3. During this task, the Luer-Lock joint 20 is divided into two parts, inasmuch as the Luer connection 14 remains associated with the further proximal end 12 of the conduit portion 3, whereas the Luer cap 11 remains fixed to the distal end 6 of the casing portion 2.

If a volume of blood coming from the patient through the cannula portion 4 penetrates the conduit portion 3, the seal 15 prevents this volume from exiting from the conduit portion 3 when the needle 7 is extracted from the seal 15 and returned inside the casing portion 2. This is possible as in the seal 15, made of resilient material, the orifice (not shown) produced there by the pointed end 129 closes once the needle 7 has been extracted.

After removing the casing portion 2, the operator can then, by means of the Luer connection 14 of the Luer-Lock joint 20, connect the conduit portion 2 on a tube (that is not shown) that conveys the blood of the patient to a haemodialyzer (that is not shown).

As previously disclosed with respect to the device 1 shown in Figures 1 to 5, after the needle 7 has again been positioned inside the casing portion 2, the pointed end 129 is no longer in contact with the external environment. This avoids accidents and allows the casing portion 2 and the needle 7 contained in the latter to be immediately disposed of as medical refuse.

Figures 22, 23 (in which the conduit portion 3 and the cannula portion 4 have been omitted for the sake of clarity) and 28 show an embodiment of the device 1 in which the needle 7 is driven easily owing to a return mechanism 122. The latter comprises a coil spring 121, that is coaxial with the needle 7 and housed inside the casing portion 2 near to the distal end 6 of the latter, a locking element 123 and a releasing element 124. The proximal end 8 of the needle 7 is provided with a pressing element 125 that is substantially cylindrical and interposed between the cursor 9 and the locking element 123. The latter comprises a rod portion 126 that is able to act as an elastic spring and terminates with an abutment 127 that is shapingly coupled with a window 128 obtained in the wall of the casing portion 2 near to the distal end 6 of the latter. In the rest configuration A, the proximal end 8 of the needle 7 is in a position near the

proximal end 5 of the casing portion 2. In this position, the abutment 127 of the rod portion 126, pressed against the wall of the casing portion 2, pushes and moves the rod portion 126 to the needle 7. When the latter, by means of the cursor 9, is pushed by the operator in the direction F1 until it exits from the free end 17 of the cannula portion 4 and the device 1 goes to the operating configuration B, the presser 125 compresses the coil spring 121. Simultaneously, the abutment 127 reaches, and, no longer retained by the wall of the casing portion 2, engages the window 128.

Once the fistula of the patient has been reached and the cannula portion 4 has been positioned, the operator can extract the needle 7 from the body of the patient automatically by acting on the locking element 123 by means of the releasing element 124. The latter comprises a lever portion 130, arranged near to the distal end 6 and pivoted on the casing portion 2 so as to define, in relation to the latter, an angle (not shown) and a plate portion 131. The operator, by acting on the lever portion 130 and/or directly on the plate 131, can shift the latter in a direction F3 that is orthogonal to the casing portion 2. In this way, the plate 131 presses on the abutment 127, disengaging it from the window 128 and pushing it inside the casing portion 2. This causes the release of the spiral spring 121, which pushes the proximal end 8 in the direction of the proximal end 5 of the casing portion 2, thus returning the needle 7 inside the latter.

In this way, the operator acts manually only to take the device 1 from the rest configuration A to the operating configuration B, whilst he can use the return mechanism 122 to return the device 1 to the rest configuration A.

With reference to Figures 26 and 27, a further embodiment of the device 1 is provided in which the conduit portion 3 is arranged parallel to the casing portion 2, which is in turn provided with the return mechanism 122 disclosed above. From the casing portion 2, near to the distal end 6 of the latter,

a connection portion 132 extends that is shaped as a hollow cylinder and is arranged obliquely. Overall, the casing portion 2 has a substantially "Y"-shaped appearance. At an end of the connection portion 132 opposite the casing portion 2 the conduit portion 3 is assembled that, near to the connection portion 132, forms an elbow 133. The conduit portion 3 is provided with a clamp (which is not shown) and an end thereof (which is not shown) opposite the connection portion 132, is provided with a Luer-Lock junction of known type.

In use, the operator, before perforating the skin of the patient at a preset point, closes the conduit portion 3 by means of the clamp and takes the device 1 manually from the rest configuration A to the operating configuration B. Thus, once the skin has been perforated and the cannula portion 4 has been positioned, he can extract the needle 7 by means of the return mechanism 122 and after opening the conduit portion 3 by acting on the clamp, may withdraw or infuse blood. In this further embodiment, usable for example in withdrawals of blood for analytical purposes and/or for administrating drugs into the circulation, the casing portion 2 need not to be disconnected from the conduit portion 3, thus reducing the number of tasks that the operator has to perform to use the device 1.

Seal means of known type, not shown, is positioned inside the casing portion 2 upstream of the zone of the latter from which the connection portion 132 leads away, and is arranged to prevent the withdrawn and/or administered fluid from being able to accidentally penetrate the casing portion 2.

In a further other embodiment, which is not shown, the "Y"-shaped device 1 is devoid of the return mechanism 122 and the needle 7 is thus driven by the operator in an exclusively manual manner.

With reference to Figures 29 and 30, a still further embodiment of the device 1 is provided comprising a further casing portion 200 and the cannula portion 4, that are

aligned on one another. Between the further casing portion 200 and the cannula portion 4 the conduit portion 3 is interposed. An end of the conduit portion 3 is coupled with the cannula portion 4 and is provided with the butterfly element 19, whilst the opposite end of the conduit portion 3 is connected to the further casing portion 200 by means of a Luer-Lock junction 90 of known type, comprising the seal 15 disclosed previously.

In the further casing portion 200, made of rigid material, a needle portion 91 is slidably insertable, comprising the needle 7, provided with the pointed end 129, and a stem 92, made of rigid material. The proximal end 8 of the needle 7 is fixed to the stem 92, which is cylinder-shaped and has a cross section of a lesser diameter than that of the cross section of the further casing portion 200.

In use, the operator, by handling the stem 92, can insert and slide the needle portion 91 inside the further casing portion 200, in such a way that the pointed end 129 of the needle 7 protrudes outside the cannula portion 4. After perforating the skin of a patient by means of the pointed end 129 and after suitably positioning the cannula portion 4, the operator, by still handling the stem 92, can remove from the cannula portion 4 the needle 7, sliding the latter in the direction of the further casing portion 200, the needle 7 being completely accommodated in the inside of the further casing portion 200.

By acting on the clamp 18, showed by a dotted line, the operator can close the conduit portion 3. Thus, owing to the presence of the Luer-Lock junction 90 of known type, the operator can remove the further casing portion 200, containing the further needle 7 from the conduit portion 3 and connect the latter to another conduit (that is not shown), for example coming from a haemodialyzer (that is not shown). After again opening the further conduit portion 3 by acting on the clamp 18, the operator can lastly carry out the

required withdrawal and/or infusion of fluids, for example blood.

The presence of the stem 92 enables the operator to extract the needle 7 from the cannula portion 4 by acting at a certain distance from the point of the body of the patient at which the cannula 4 is inserted, and thus making the aforementioned extraction less unpleasant for the patient.

With reference to Figure 17, a grip element 70 is provided that is associable with the device 1 and usable instead of the butterfly element 19. The grip element 70, made of, for example, soft PVC, comprises a parallelepiped-shaped body 71. From opposite ends of the body 71 a proximal conduit 72 and a distal conduit 73 lead away, both proximal conduit 72 and distal conduit 73 being aligned on a longitudinal axis X of the body 71. Two wings 74, 75, approximately trapezium-shaped, are fixed to opposite sides of the body 71 and are arranged orthogonally to the latter. In use, into the distal conduit 73 the proximal end 16 of the cannula portion 4 is inserted and into the proximal conduit 72 the distal end 13 of the conduit portion 3 is inserted.

In the wing 75 a projection 75a is obtained arranged parallel to the longitudinal axis X of the body 71 and approximately semicylinder-shaped. The projection 75a, in use, is received in a shapingly coupled manner by a corresponding recess 74a, obtained in the wing 74 and arranged parallel to the longitudinal axis X of the body 71. A connecting portion 76, made as a flexible and "C"-shaped plate having a concavity facing the proximal conduit 72, connects an oblique edge 74b of the wing portion 74 with an oblique edge 75b of the wing portion 75, the oblique edge 74b and the oblique edge 75b both being opposite the distal conduit 73. In a substantially median zone of the connecting portion 76 a groove 77 is obtained having a cross section that is semi-circular and aligned on the longitudinal axis X of the body 71.

In use, when the operator grasps and clamps together the wing portions 74, 75 of the grip element 70 to direct the needle 7

to a prefixed anatomical region of a patient, the connecting portion 76 is clamped around the conduit portion 3, which is received in the groove 77. In this way, the operator can more effectively and securely handle the device 1, inasmuch as he acts on several portions of the latter simultaneously. Furthermore, the presence of the recess 74a and of the corresponding projection 75a enables the operator to clamp together the wing portions 74 and 75 more effectively.

The grip element 70 can be used instead of the butterfly element 19 also in infusion and/or withdrawal needle devices that are different from the device 1. In this case, instead of the cannula portion 4, the needle can be associated directly with the distal conduit 73.

With reference to Figures 24 and 25, a further cannula portion 140 is provided, comprising a straight portion 141 and a deflected portion 142, that partially run in a reciprocally parallel manner.

The straight portion 141, shaped as a cylindrical tube, has a further fixed end 143 that is fixable to the further distal end 13 of the conduit portion 3 of the device 1, and a further free end 144, opposite the further fixed end 143.

The deflected portion 142 has a further other fixed end 145, and a further other free end 146, opposite the further other fixed end 145. The further other fixed end 145 is fixable to a further other distal end 151 of a connecting tube 150, a further other proximal end 152 of which can be connected, by a Luer connection 14 of known type, to a further pipe, which is not shown. The deflected portion 142 comprises, in succession, a first deflected portion 147, defining in relation to the straight portion 141 an angle H less than 90°, a straight portion 148, running parallel to the straight portion 141, and a second deflected portion 149, defining in relation to the straight portion 141 a further angle W that is less than 90° and having a size that is approximately the same as that of the angle H. When the further cannula 140 is

associated with the device 1, the straight portion 140 is aligned on the conduit portion 3 and on the casing portion 2.
In further embodiments of the further cannula 140, which are not shown, the angle H and the further angle W can have a size comprised between 0° and 90°.
In use, the further cannula portion 140 can be effectively associated with each of the provided embodiments of the device 1 disclosed above, being particularly effective for simultaneously carrying out withdrawing and reinfusion during haemodialysis.
If the operator uses the device 1 provided with the further cannula 140, it is sufficient to insert the needle 7 just once into the body of the patient to suitably position in the latter both the straight portion 141 and the deflected portion 142. In fact, when the needle 7 directly inserted into the straight portion 141 penetrates the body of the patient, the needle 7 also drags the deflected portion 142 therewith.
As a result, during haemodialysis, through the straight portion 141 a certain volume of blood is withdrawn from the patient, in a direction F4, to the device 1, and from the device 1 it is conveyed to the haemodialyzer. The same volume of blood, once it has been treated, can be reinfused into the patient by connecting the tube emerging from the haemodialyzer to the connecting tube 150, that can be kept closed by means of a clamp 18, showed by a dotted line, until the treated blood arrives from the haemodialyzer. The latter thus travels along the deflected portion 142 in a direction F5 opposite the direction F4 and is delivered into the body of the patient near to the further other free end 146.
In this way, during haemodialysis, it is not necessary to use a pair of devices 1, inasmuch as one of these, if provided with the further cannula portion 140, is usable both for withdrawing the blood and for reinfusing the latter into the patient. This enables waste of disposable material during

haemodialysis to be reduced and the number of tasks that the operator has to perform to be reduced.

Furthermore, the further cannula portion 140 is more effective also than needles connectable to a double external conduit provided by the prior art, inasmuch as the latter, whilst enabling a single hollow needle to be used during haemodialysis, are nevertheless rigid elements inserted into the body of the patient and which the latter has to bear until the end of the procedure.

The device 1 disclosed above, although it is disegned particularly to conduct haemodialysis, can be effectively used also for conducting treatments other than haemodialysis but which, like the latter, require fluids to be withdrawn from and/or infused into a patient, and for administering drugs in liquid form to a patient.

CLAIMS

1. Device (1), comprising needle means (7) and cannula means (4) arranged for removably receiving said needle means (7) in the inside thereof, characterised in that it furthermore comprises casing means (2; 2a; 2b; 200) connected to said cannula means (4) and configured in such a way that said needle means (7) can be received in said casing means (2; 2a; 2b; 200).

2. Device according to claim 1, furthermore comprising locking means (35; 35a), associated with said needle means (7) and shaped in such a way as to be able to lock said needle means (7) inside said casing means (2; 2a; 2b; 200).

3. Device according to claim 1, or 2, wherein said casing means (2; 2a; 2b; 200) is situated in a position opposite a free end (17) of said cannula means (4).

4. Device according to any preceding claim, wherein said casing means (2; 2a; 2b; 200) is aligned on said cannula means (4).

5. Device according to any preceding claim, wherein said casing means (2; 2a; 2b; 200) is shaped in such a way as to make a pointed end (129) of said needle means (7) inaccessible from the outside when said needle means (7) is contained in said casing means (2; 2a; 2b).

6. Device according to any preceding claim, wherein conduit means (3) is interposed between said casing means (2; 2a; 2b; 200) and said cannula means (4).

7. Device according to claim 6, wherein said casing means (2; 2a; 2b; 200) is connected to said conduit means (3) through connecting means (20; 132; 90; 46).

8. Device according to claim 7, wherein said connecting means (20; 132; 90; 46) comprises a Luer-Lock connection (20; 90; 46) interposed between said conduit means (3) and said casing means (2; 2a; 2b; 200) and provided with seal means (15) made of resilient material.

9. Device according to claim 7, or 8, wherein said casing means (2; 2a; 2b; 200) is separable from said conduit means (3) after use.

10. Device according to any preceding claim, wherein said casing means (2; 2a; 2b; 200) comprises a flexible casing (2) formed of reciprocally assembled slat elements (21, 22).

11. Device according to claim 10, wherein said slat elements (21, 22) are spaced apart from one another so as to define, in said flexible casing (2), longitudinal slot means (33) arranged for containing said needle means (7).

12. Device according to claim 11, as appended to claim 8, wherein semiconical end portions (25b) that are comprised in said slat elements (21, 22) and are reciprocally juxtaposed form a male Luer connection comprised in said Luer-Lock connection (46).

13. Device according to claim 12, wherein in said male Luer connection ring seal means is received.

14. Device according to any one of claims 10 to 13, wherein a proximal end (8) of said needle means (7), opposite said pointed end (129), is associated with cursor means (36), arranged for sliding, in use, in said longitudinal slot means (33).

15. Device according to claim 14, wherein said cursor means (36) is associated with said locking means (35; 35a).

16. Device according to any one of claims 11 to 15, wherein said locking means (35; 35a) comprises grip portions (37, 38), arranged outside said longitudinal slot means (33) and handleable, during use, by an operator.

17. Device according to claim 16, wherein, in said grip portions (37, 38), hook means (44, 44a) is obtained that is arranged for engaging, in use, corresponding appendage means (29, 29a) comprised in an end portion (5) of said flexible casing (2) opposite said cannula means (4).

18. Device according to claim 17, wherein, when said hook means (44, 44a) engages said appendage means (29, 29a), said needle means (7) is locked inside said flexible casing (2).

19. Device according to claim 17, or 18, wherein said grip portions (37, 38) furthermore comprise further hook means (45, 45a) arranged for engaging, in use, a further end portion (6) of said flexible casing (2), opposite said end portion (5).

20. Device according to claim 19, wherein said further end portion (6) comprises an edge (47a) of ring nut means (47) associated with said flexible casing (2).

21. Device according to claim 19, or 20, wherein when said further hook means (45, 45a) engages said further end portion (6), said needle means (7) is arranged outside said flexible casing (2) and is locked in a position wherein said pointed end (129) protrudes outside said distal end (17).

22. Device according to any one of claims 16 to 21, as appended to claim 14, wherein said grip portions (37, 38) are connected to said cursor means (36) by means of flexible connecting portions (39, 40).

23. Device according to any one of claims 16 to 22, wherein said grip portions (37, 38) furthermore comprise guiding means (49, 50), arranged for guiding sliding of said locking means (35; 35a) along said flexible casing (2).

24. Device according to claim 23, wherein said guiding means (49, 50) is shaped in such a way as to be able to embrace transversely, at least in part, said flexible casing (2).

25. Device according to any one of claims 11 to 24, wherein said flexible casing (2) is provided with a tubular element (51), said tubular element (51) being slidable on said flexible casing (2) and having a cavity communicating with said longitudinal slot means (33).

26. Device according to claim 25, wherein said needle means (7) is fixed to an end portion (51a) of said tubular element (51) opposite said cannula portion (4).

27. Device according to any preceding claim, wherein said casing means (2; 2a; 2b; 200) comprises a foldable casing (2a) provided with a bellows wall (61).

28. Device according to claim 27, as appended to claim 19, wherein said locking means (35a) is provided only with said further hook means (45, 45a).

29. Device according to any preceding claim, wherein said casing means (2; 2a; 2b; 200) comprises a telescopic casing (2b) formed by a plurality of coaxial tubular portions (65, 66, 67).

30. Device according to claim 29, wherein said telescopic casing (2b) is provided with projecting locking means arranged for being received, in use, in window means (65a, 66a), said projecting locking means and said window means (65a, 66a) being obtained in corresponding portions of said plurality of coaxial tubular portions (65, 66, 67).

31. Device according to claim 29, or 30, wherein said plurality of coaxial tubular portions (65, 66, 67) comprises a tubular end portion (67) provided with a disc element (68) that is graspable, during use, by an operator.

32. Device according to any preceding claim, wherein through-hole means (6) is obtained in said cannula means (4), said through-hole means (60) being arranged for promoting and increasing the transit of fluids through said cannula means (4).

33. Device according to claim 32, wherein said through-hole means (60) is received in reciprocally opposite portions of said cannula means (4).

34. Device according to claim 32, or 33, wherein said through-hole means (60) is received in reciprocally staggered portions of said cannula means (4).

35. Device according to any one of claims 32 to 34, as appended to claim 6, wherein longitudinal notch means (48) is obtained in said needle means (7), said longitudinal notch means (48) being arranged for receiving a volume of said fluids through said through-hole means (60) and conveying said volume to said conduit means (3), so as to enable an operator, in use, to check whether said needle means (7) is correctly positioned.

36. Device according to any preceding claim, wherein said casing means (2; 2a; 2b; 200) has a tubular shape.

37. Device according to any preceding claim, wherein said casing means (2; 2a; 2b; 200) is made of a rigid material.

38. Device according to claim 37, as appended to claim 7, wherein said connecting means (20; 132; 90; 46) comprises connecting conduit means (132), protruding from said casing means (2; 2a; 2b; 200) in such a way as to define with the latter an approximately Y-shaped structure.

39. Device according to claim 37, or 38, wherein said needle means (7) is provided with further cursor means (9), said further cursor means (9) protruding outside through groove means (10) obtained in said casing means (2; 2a; 2b; 200) and being handleable, during use, by an operator.

40. Device according to any one of claims 37 to 39, wherein said casing means (2; 2a; 2b; 200) is provided with recovering means (122) arranged for enabling said needle means (7) to reenter said casing means (2; 2a; 2b; 200) automatically.

41. Device according to any preceding claim, wherein said needle means (7) is fixed to stem means (92), by means of which said needle means (7) is insertable into said casing means (200).

42. Device according to claim 41, wherein said stem means (92) extends along the entire length of said casing means (200).

43. Device according to any preceding claim, wherein, in said cannula means (4), first transit conduit means (141) and second transit conduit means (142) are obtained that are shaped in such a way as to enable said cannula means (4) to withdraw a fluid substance from an anatomical region through said first transit conduit means (141), and to infuse into said region said fluid substance through said second transit conduit means (142), or vice versa.

44. Grip means, arranged for being coaxially associated with needle means comprised in a device for withdrawing and/or infusing fluids and comprising a hollow body (71) interposed between flexible wing portions (74a, 74b) fixed on opposite sides of said hollow body (71), characterised in that said wing portions (74a, 74b) are connected together by a flexible connecting portion (76), shaped in such a way as to be able to surround a portion of said device at least partially.

45. Grip means according to claim 44, comprising conduit means (72) protruding from an end portion of said hollow body (71) and aligned on a longitudinal axis (X) of said hollow body (71).

46. Grip means according to claim 45, furthermore comprising further conduit means (73), aligned on said longitudinal axis (X) and protruding from said hollow body (71) in an opposite position to said conduit means (72).

47. Grip means according to any one of claims 44 to 46, wherein, in said connecting portion (76) channel means (77) is obtained that is arranged for receiving said adjacent portion of said device.

48. Grip means according to any one of claims 44 to 47 comprised in a device according to any one of claims 1 to 43.

49. Cannula means (140), arranged for penetrating an anatomical region and being traversed by a fluid substance, characterised in that it comprises first transit conduit means (141) and second transit conduit means (142) shaped in such a way as to enable said cannula means (140) to withdraw said substance from said region through said first transit conduit means (141), and infuse said fluid substance into said region through said second transit conduit means (142), or vice versa.

50. Cannula means according to claim 49, wherein said first transit conduit means (141) is rectilinear.

51. Cannula means according to claim 49, or 50, wherein said second transit conduit means (142) has a rectilinear portion (148) associated with a first oblique portion (147) and a second oblique portion (149).

52. Cannula means according to claim 51, wherein said straight portion (148) is interposed between said first oblique portion (147) and said second oblique portion (149).

53. Cannula means according to any one of claims 49 to 52, comprised in a device according to any one of claims 1 to 42.

54. Method for conducting haemodialysis in a patient, comprising:

-inserting needle means (7) in a portion of the vascular apparatus of said patient, said needle means (7) being arranged inside cannula means (4);

-slidably removing said needle means (7) from said cannula means (4), leaving said cannula means (4) inserted into said portion;

-connecting said patient, by said cannula means (4), to an apparatus for haemodialysis.

55. Method according to claim 61, wherein said removing comprises inserting said needle means (7) into casing means (2; 2a; 2b; 200) connected to said cannula means and arranged for keeping said needle means (7) separate from the external environment.

56. Method according to claim 62, furthermore comprising removing said casing means (2; 2a; 2b; 200) from said cannula means (4), after said needle means (7) has been inserted into said casing means (2; 2a; 2b; 200).

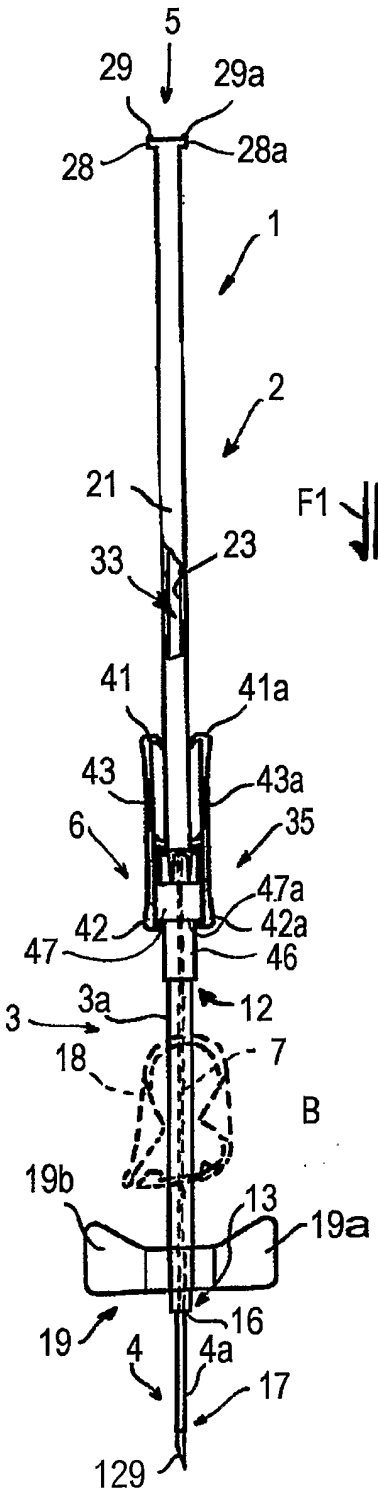


Fig. 1

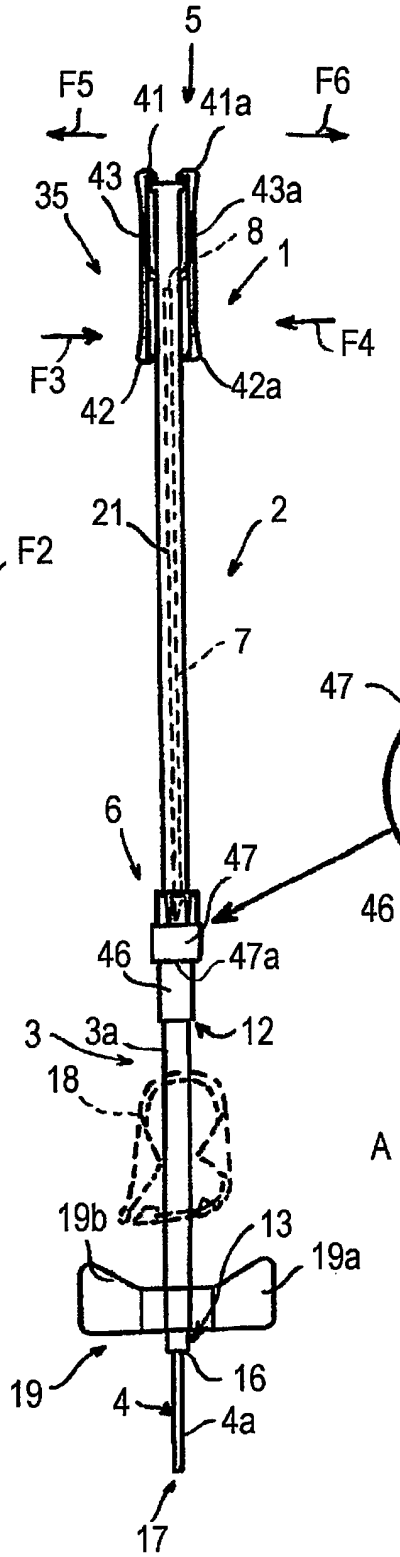


Fig. 2

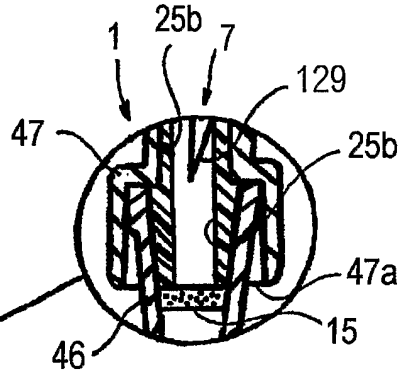


Fig. 3

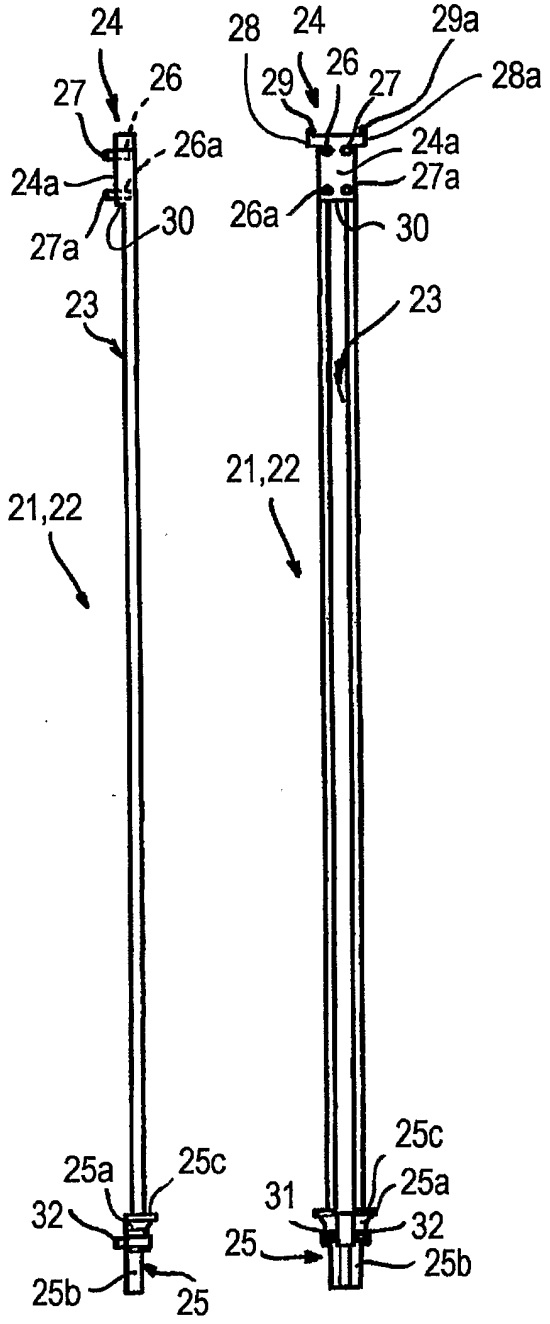


Fig. 4 Fig. 5

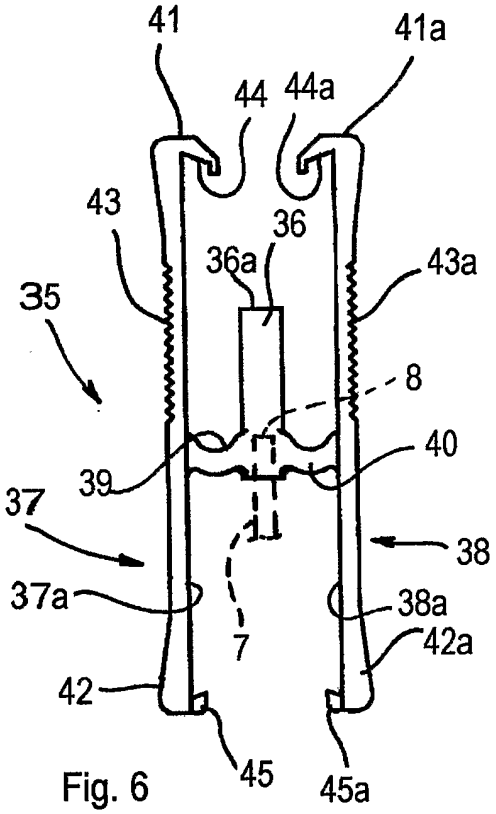


Fig. 6

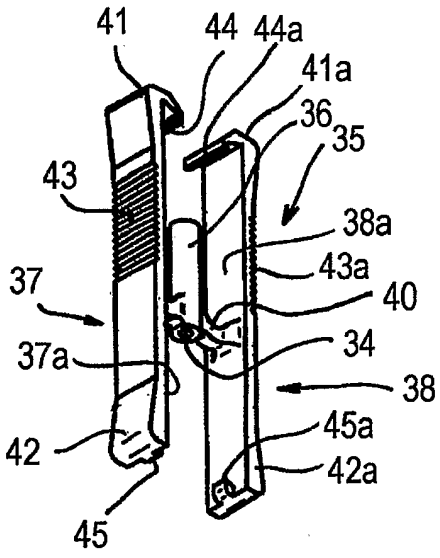


Fig. 7

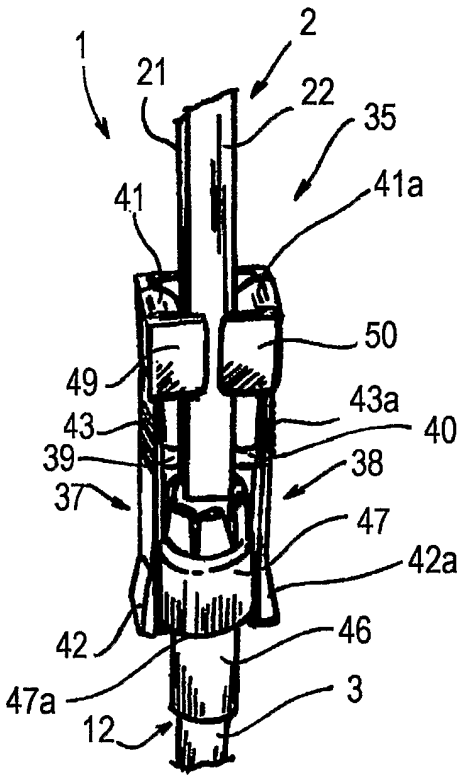
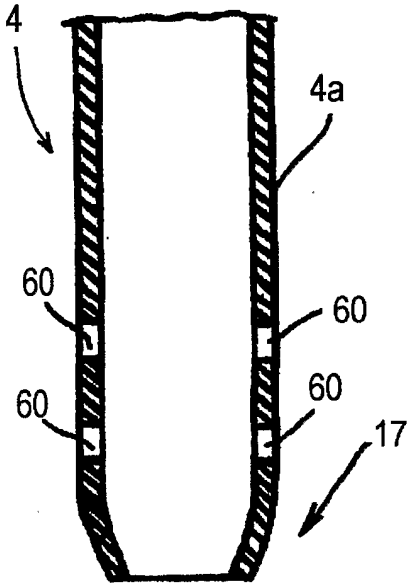


Fig. 11



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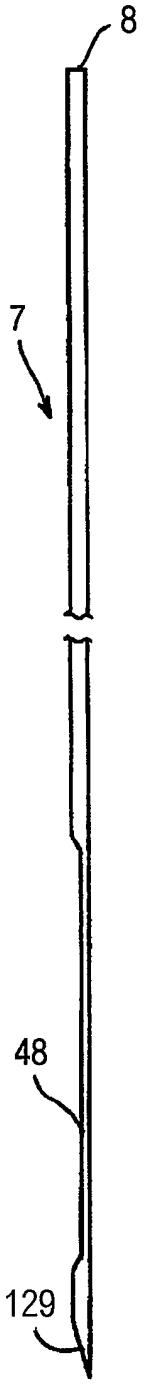

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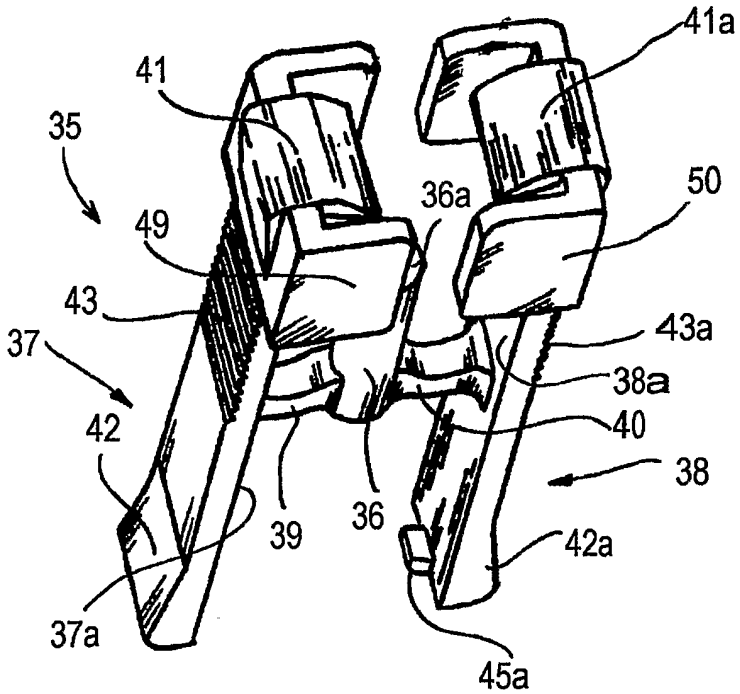
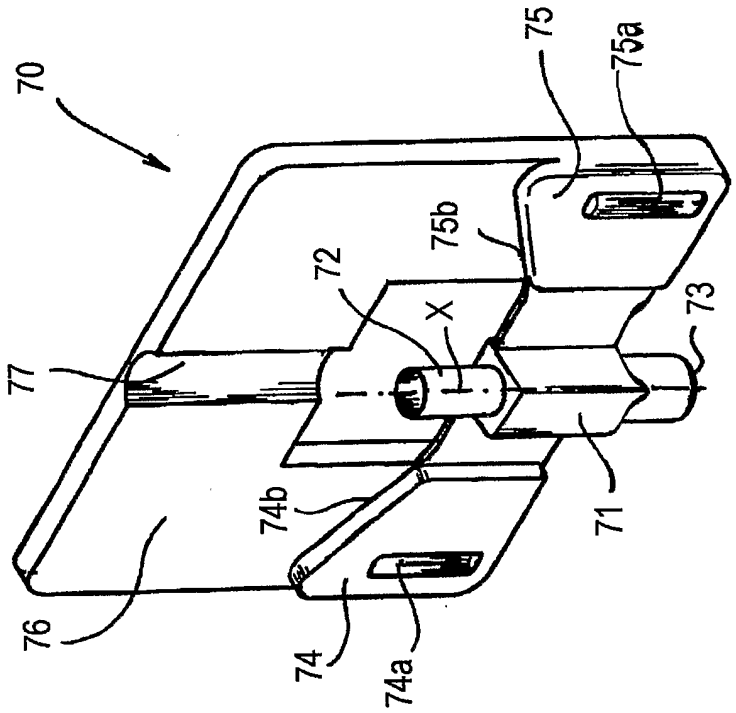


Fig. 10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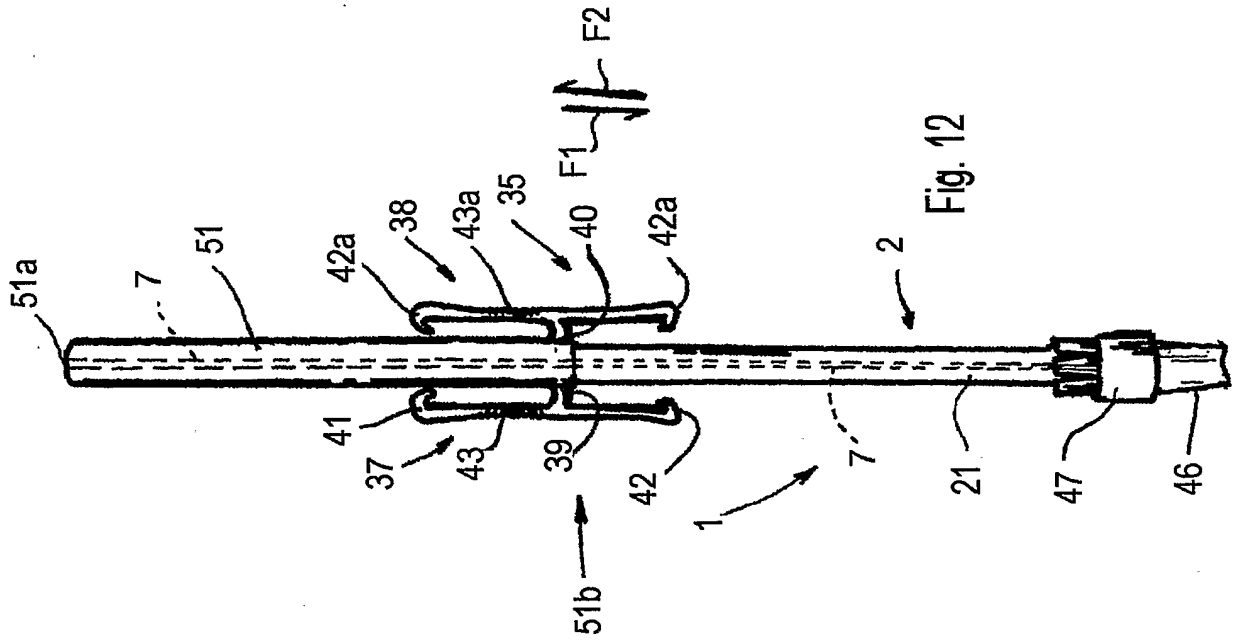
74
74a

Fig. 17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7'
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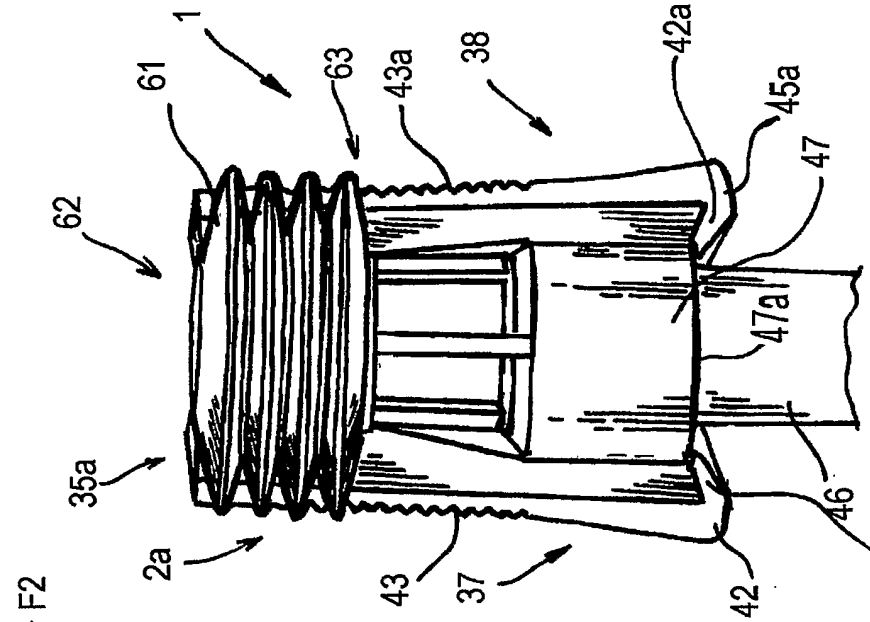
47
46
51b

Fig. 12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45
F2
F1

Fig. 13

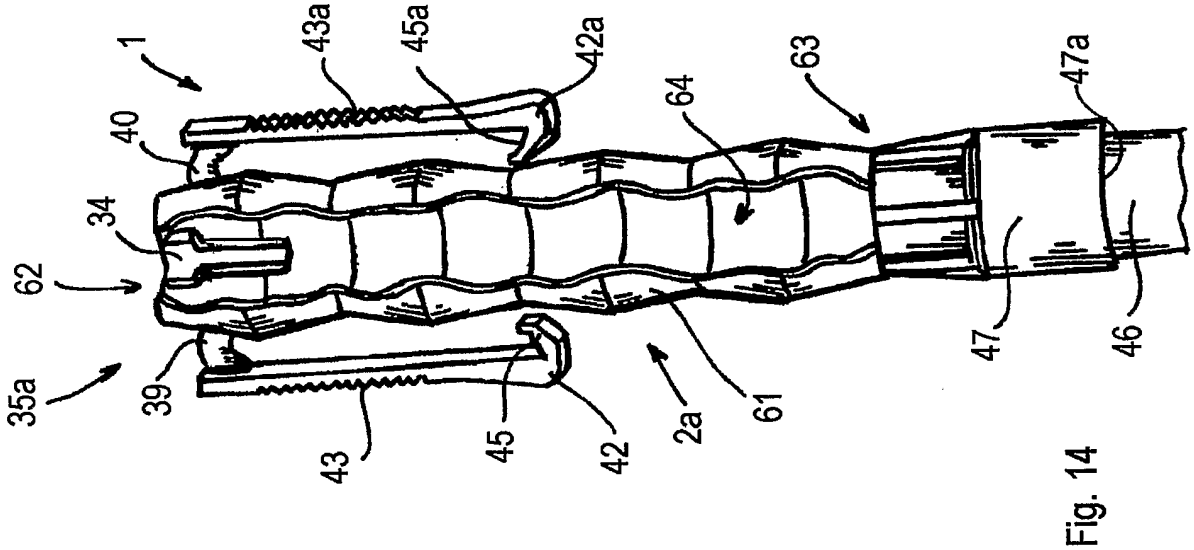
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Fig. 14

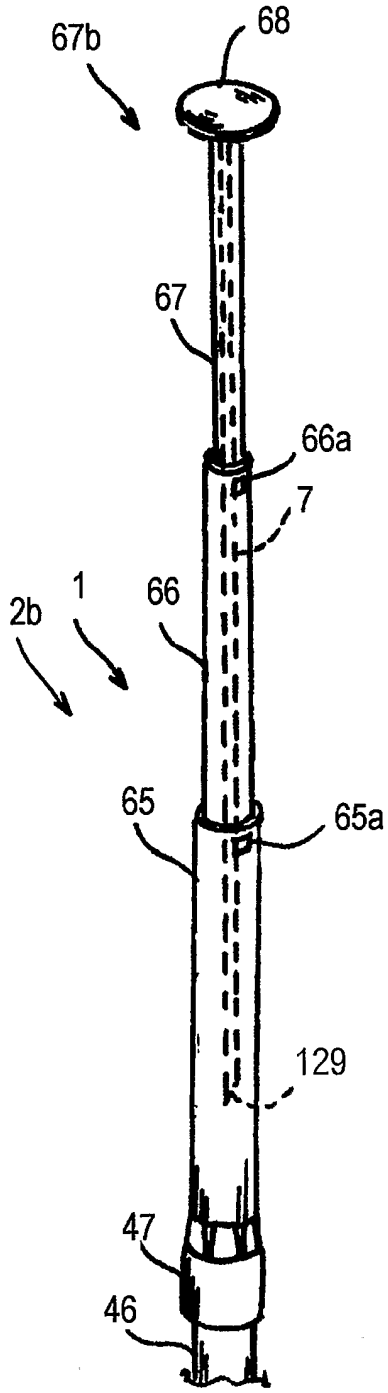
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Fig. 15

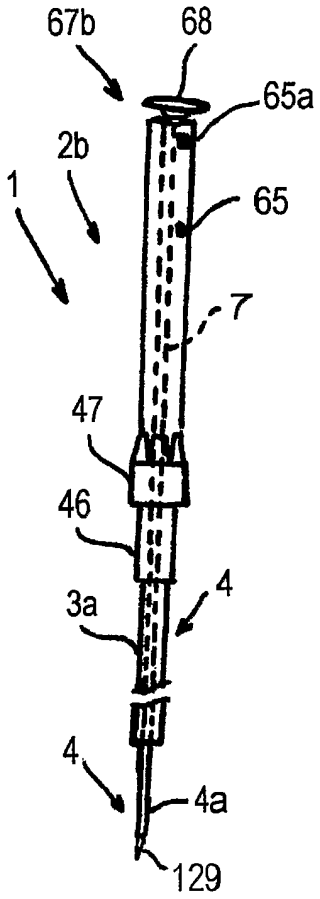
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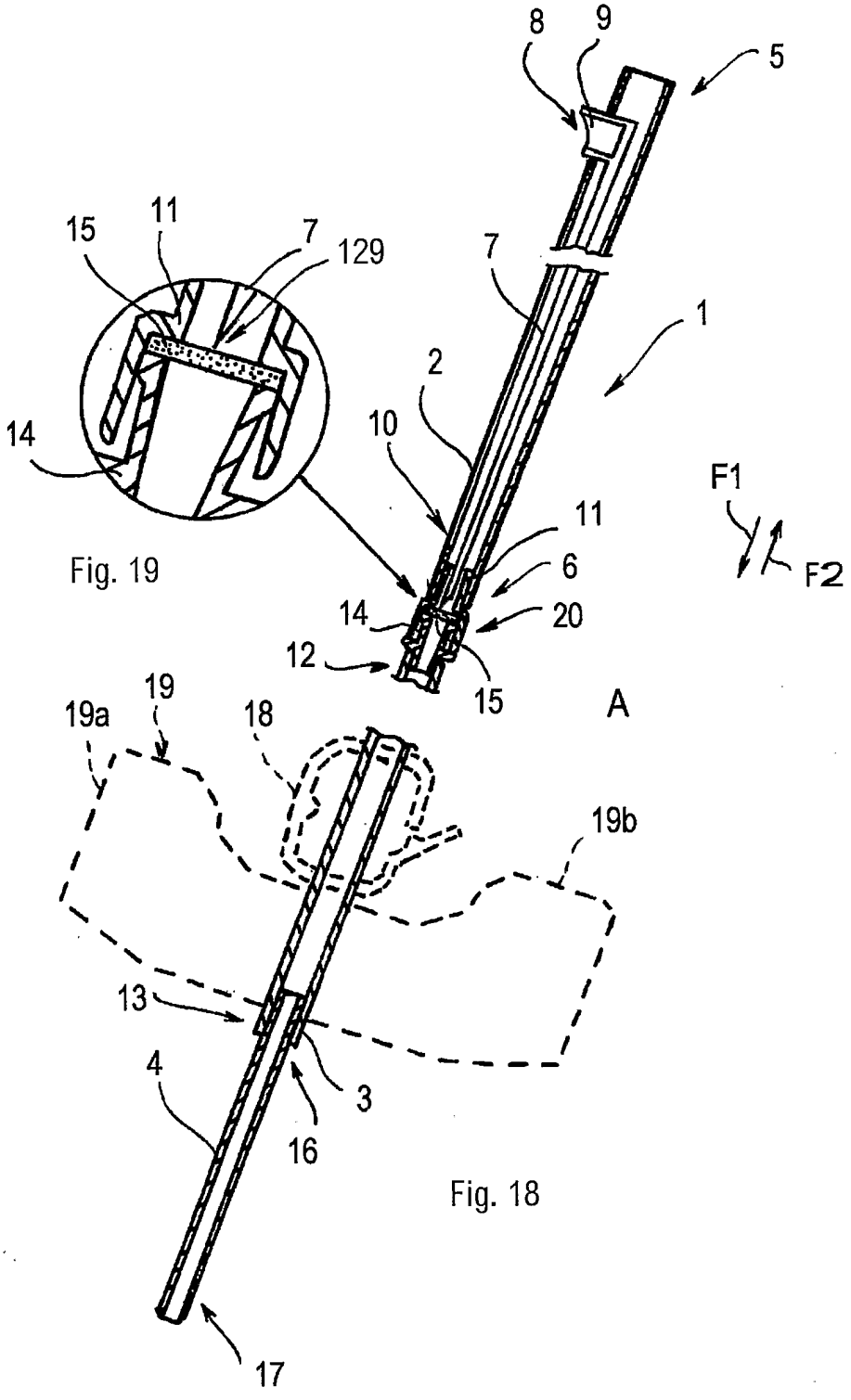
Fig. 16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19
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Fig. 19

Fig. 18

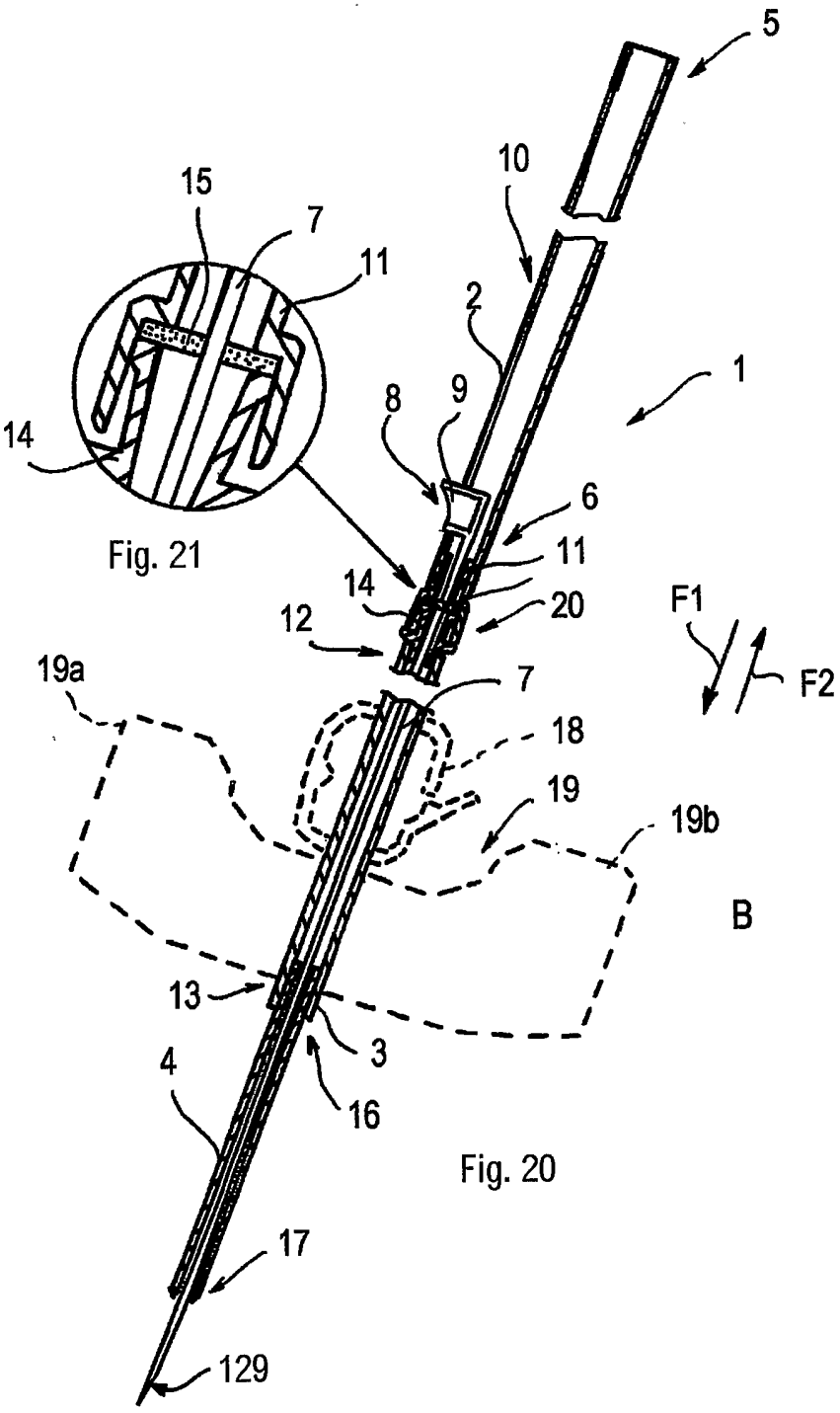
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Fig. 21

Fig. 20

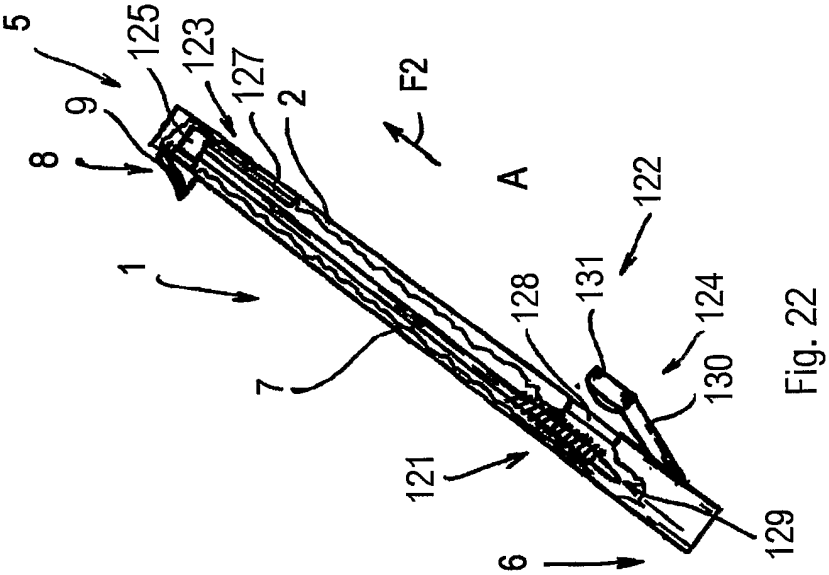
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Fig. 22

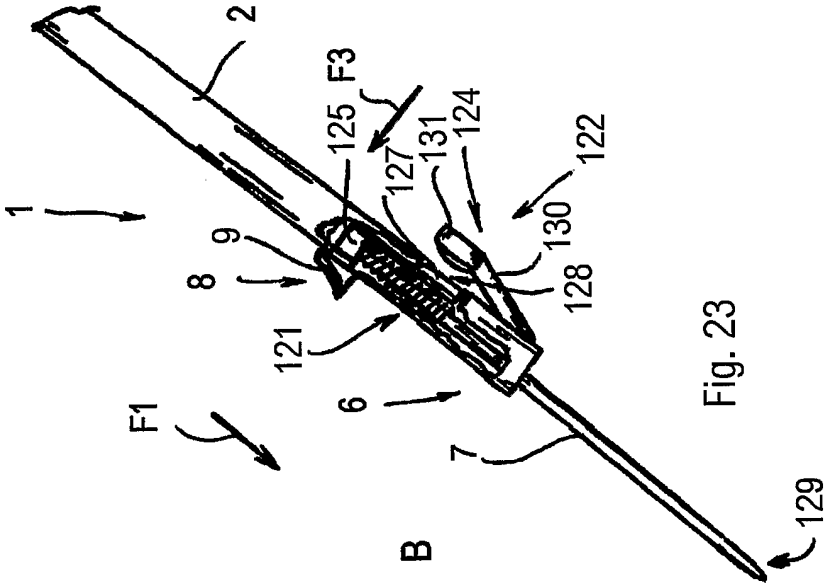
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Fig. 23

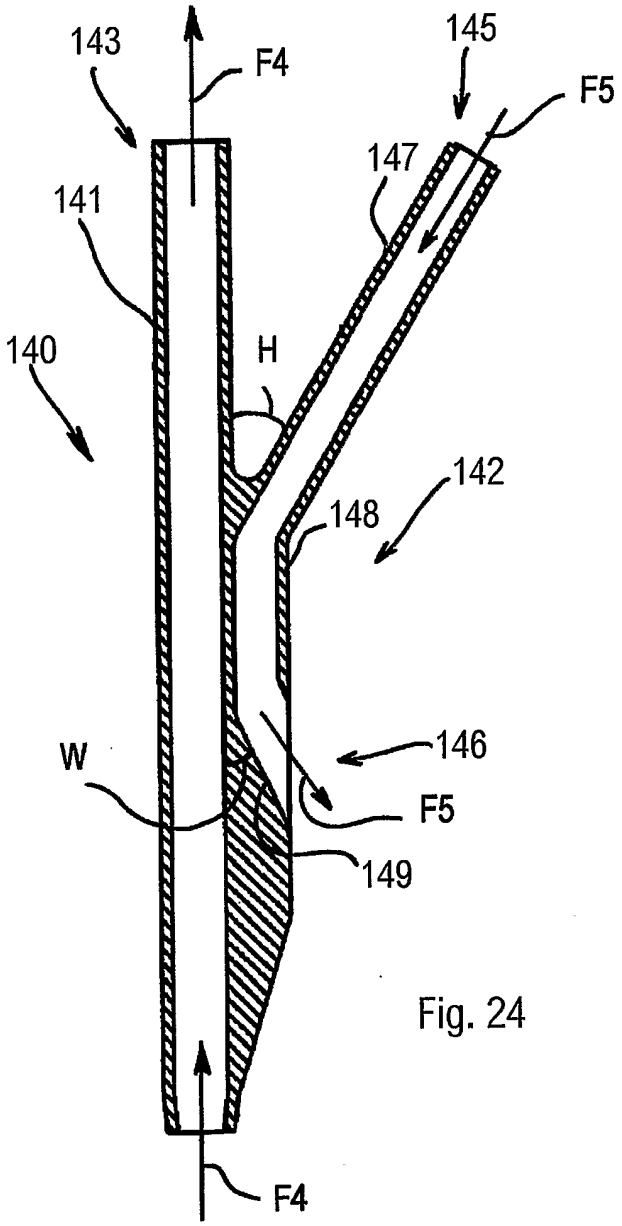

Fig. 24

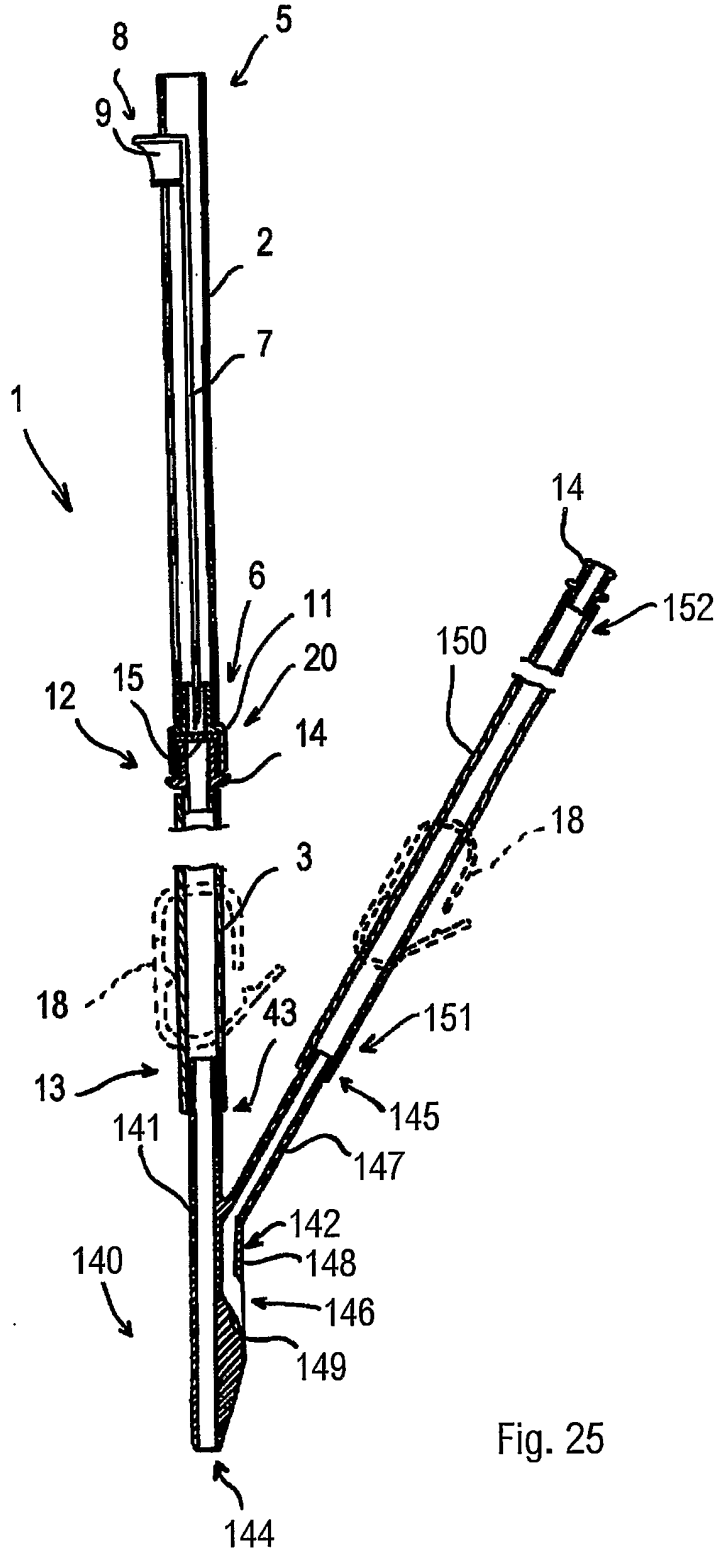
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Fig. 25

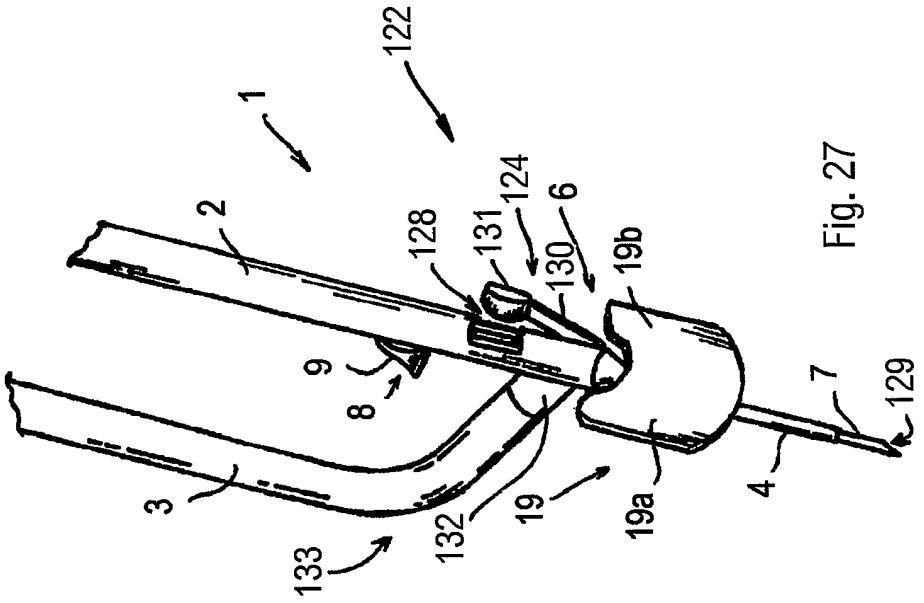
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Fig. 27

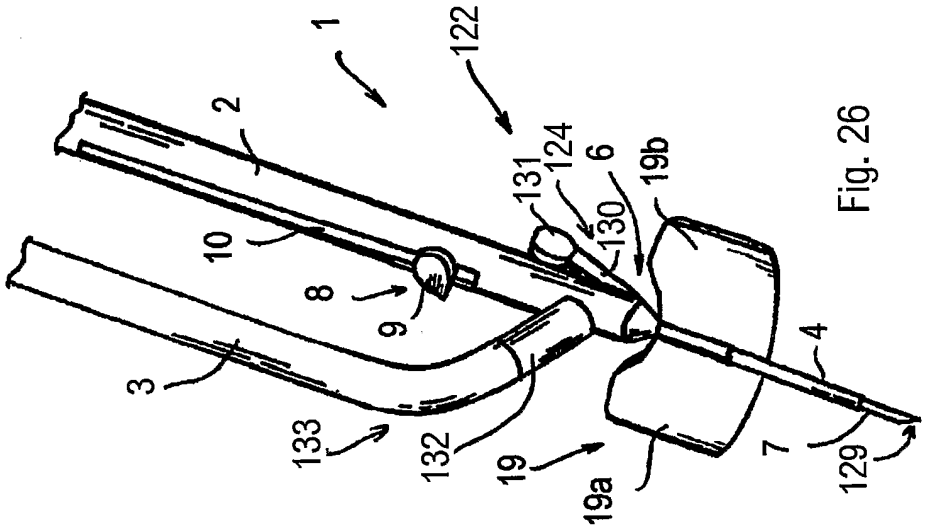
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Fig. 26

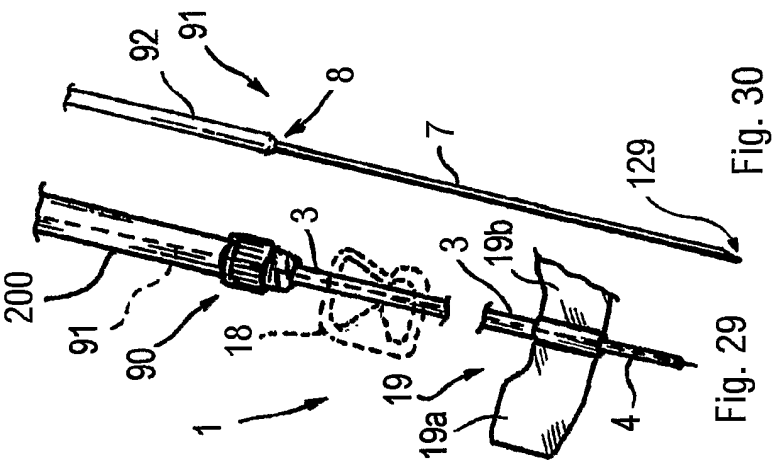

Fig. 30

Fig. 29

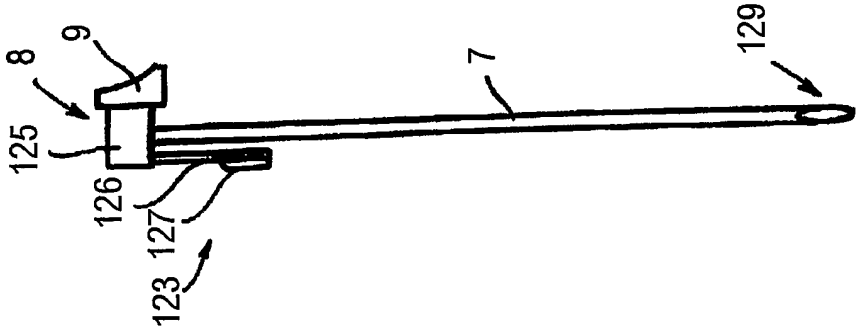

Fig. 28