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(54) Title: NEEDLE TIP PROTECTOR

(57) Abstract: The present disclosure is directed to an indwelling needle set which includes a needle tip protector device which adds a minimal length to the needle set to maintain operability of the device. To accomplish this, a needle tip protector device is provided for releasable attachment to the needle set. The protector device includes a body and a protecting sleeve which is movable through an opening in the body from an advanced position located substantially within the body to a retracted position extending rearwardly from the body. The protecting sleeve is dimensioned to slidably receive a puncturing needle which includes an increased diameter position which cannot be withdrawn through the protecting sleeve.

NEEDLE TIP PROTECTOR

BACKGROUND

1. Technical Field

The invention relates to a needle tip protector device which is mounted about a puncturing part of a puncturing needle after the puncturing needle has been removed from an indwelling needle.

2. Background of the Art

It is conventional to use an indwelling needle to supply a predetermined medicinal liquid and the like to the blood vessels of a patient to perform a medical procedure, such as artificial dialysis. The indwelling needle used in such a case includes a cannula for positioning a needle tip within the blood vessel of the patient and a body portion connected to the basal end portion of the cannula. In order to position the tip end of the cannula within a blood vessel, a puncturing needle is provided to pierce the body to facilitate smooth manipulation of the cannula into the blood vessel. When the manipulation described above is carried out, the puncturing needle is inserted into the indwelling needle such that the tip of the puncturing needle projects slightly from the tip end portion of the cannula. In that condition, the cannula together with the puncturing needle is inserted into the blood vessel. After the cannula is positioned within the blood vessel, the puncturing needle is pulled out of the indwelling needle and blood vessel and the rear end portion of the indwelling needle is connected to a tube member or the like for supplying the predetermined medicinal liquid to or from the blood vessel.

Such an indwelling needle set includes a needle tip protector for preventing the needle tip of the puncturing needle which is removed from the cannula from injuring the patient or the like (for example, see Patent Literature 1). The needle tip protector is formed by a cylinder comprising one end having an opening having a large inner diameter and the other end having an opening having a small inner diameter. The tip end portion of the puncturing needle to be protected by the needle tip protector is formed so as to have a size to allow passage of the puncturing needle through the large diameter opening of the needle tip protector but prevent passage of the puncturing needle through the small diameter opening of the needle tip protector. A rear portion of the puncturing needle is formed or is dimensioned to permit insertion through

the small diameter opening. Therefore, when the puncturing needle is pulled rearwardly relative to the needle tip protector while the large diameter opening is opposed to the tip end portion of the puncturing needle and the rear portion of the puncturing needle is positioned though the small diameter opening, the needle tip protector will be engaged by the tip end portion of the puncturing needle such that the tip of the puncturing needle is covered by the needle tip protector.

Although, the conventional needle tip protector described above can not be removed from the tip end portion of the puncturing needle, the protector has a tendency to move towards the rear portion of the puncturing needle thus, exposing the tip end portion of the puncturing needle. Therefore, a needle tip protector capable of securely covering the tip end portion of the puncturing needle by fixing it to the tip end portion of the puncturing needle has been developed. One drawback of such a needle tip protector, however, is that the operationality of the needle tip protector may be negatively affected because the combination of the puncturing needle and the cannula and the like installed into the indwelling needle increases the length of the indwelling needle set.

SUMMARY

The present disclosure provides a needle tip protection device which includes a needle tip protector body having a front portion configured to receive the rear end of an outer needle and a rear portion defining a rearwardly extending engagement tube defining a hole. A stopper member is supported within the rear portion of the needle tip protector body. The stopper member is movable from a first position obstructing the hole of the engagement tube to a second position providing access to the hole of the engagement tube. A protecting sleeve is slidably positioned within the hole of the engagement tube between an advanced position located substantially within the needle tip protector body and a retracted position extending rearwardly from the needle tip protector body through the hole of the engagement tube. The protecting sleeve has a forward end and a rear end. The rear end of the protecting sleeve is dimensioned to be slidably received in the hole of the engagement tube and the forward end of the protecting sleeve is dimensioned to prevent passage of the forward end of the protecting sleeve through the hole of the engagement tube. The protecting sleeve defines a bore having a forward opening having a first diameter and a rear opening having a second diameter smaller than the first diameter.

In one embodiment, the stopper member defines a hole which is aligned with the hole in the engagement tube when the stopper member is in its second position and misaligned with the hole in the engagement tube when the stopper member is in its first position. The hole in the stopper member is dimensioned to permit passage of the protector sleeve. The stopper member may be urged to its first position by a spring, e.g., a coil spring.

In one embodiment, the needle tip protector body further includes a diaphragm separating the front portion of the needle tip protector body and the rear portion of the needle tip protector body. The diaphragm defines an insertion hole which is aligned with the hole in the engagement tube.

The stopper member may include an engagement piece configured to secure the needle tip protector body to a needle housing of an indwelling needle set when the stopper member is in the second position. The engagement piece of the stopper member can include an engagement claw.

In one embodiment, the protecting sleeve extends through the hole in the stopper member when the protecting sleeve is in the advanced position and engages the walls of the sleeve defining the hole in the stopper member to retain the stopper member in its second position. The walls of the sleeve defining the hole in the stopper member may be convex.

In one embodiment, the hole in the engagement tube defines a stepped bore, wherein a rear portion of the stepped bore has a diameter which is smaller than a diameter of a forward portion of the stepped bore. A step may be defined between the forward portion of the stepped bore and the rear portion of the stepped bore, such that the rear end of the protecting sleeve engages the step when the protecting sleeve is in its retracted position.

The present disclosure also provides an indwelling needle set including an outer needle having a cannula and a housing body defining a chamber. An elastic valve is supported within the chamber. An inner needle has a forward puncturing end and a rear end. The forward puncturing end has an enlarged diameter portion. The needle set also includes a needle tip protection device comprising a needle tip protector body having a front portion configured to receive the rear end of the housing of the outer needle and a rear portion defining a rearwardly extending engagement tube defining a hole. A stopper member is supported

within the rear portion of the needle tip protector body, the stopper member is movable from a first position obstructing the hole of the engagement tube to a second position providing access to the hole of the engagement tube. A protecting sleeve is slidably positioned within the hole of the engagement tube between a advanced position located substantially within the needle tip protector body and a retracted position extending rearwardly from the needle tip protector body through the hole of the engagement tube. The protecting sleeve has a forward end and a rear end, the rear end is dimensioned to be slidably received in the hole of the engagement tube and the forward end is dimensioned to prevent passage of the forward end of the protecting sleeve through the hole of the engagement tube. The protecting sleeve defines a bore having a forward opening having a first diameter and a rear opening having a second diameter smaller than the first diameter. The inner needle is slidably positioned within the protecting sleeve. The enlarged diameter portion of the inner needle is greater in diameter than the second diameter of the rear opening of the protecting sleeve such that the inner needle cannot be withdrawn from the rear end of the protecting sleeve.

In one embodiment, a tube insertion portion is movably supported within the housing. The tube insertion portion defines a bore and is movable from a rearward position to a forward position, wherein an insertion end of the tube insertion portion extends through an opening in the elastic valve. The tube insertion portion may be urged towards its rearward position by a spring.

In one embodiment, the housing body includes an external thread adapted to engage a tube member for supplying medicinal fluid to the needle set. The inner needle may include a hub member supported on a rear end of the inner needle.

In one embodiment, the stopper member defines a hole which is aligned with the hole in the engagement tube when the stopper member is in its second position and misaligned with the hole in the engagement tube when the stopper member is in its first position. The hole in the stopper member is dimensioned to permit passage of the protector sleeve. The stopper member may be urged to its first position by a coil spring.

In one embodiment, the needle tip protector body includes a diaphragm separating the front portion of the needle tip protector body and the rear portion of the needle tip protector body. The diaphragm defines an insertion hole which is aligned with the hole in the engagement tube.

The stopper member may include an engagement piece configured to secure the needle tip protector body to the housing body of the outer needle when the stopper member is in the second position. The engagement piece of the stopper member can be in the form of an engagement claw and the housing body of the outer needle can include a projection. The engagement claw is positioned to engage the projection when the stopper member is in its second position to secure the needle tip protector body to the housing body and to disengage the projection when the stopper member is in its first position to detach the needle tip protector body from the housing body.

In one embodiment, the protecting sleeve extends through the hole in the stopper member when the protecting sleeve is in the advanced position and engages walls of the sleeve defining the hole in the stopper member to retain the stopper member in its second position. The walls of the sleeve defining the hole in the stopper member may be convex.

In one embodiment, the hole in the engagement tube defines a stepped bore. A rear portion of the stepped bore has a diameter which is smaller than a diameter of a forward portion of the stepped bore. A step may be defined between the forward portion of the stepped bore and the rear portion of the stepped bore, wherein the rear end of the protecting sleeve engages the step when the protecting sleeve is in its retracted position.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the presently disclosed needle tip protection device in association with an indwelling needle set are disclosed herein with reference to the drawings, wherein:

Fig. 1 is a side view illustrating an indwelling needle set including one embodiment of the presently disclosed needle tip protector device;

Fig. 2 is a front view of the indwelling needle set shown in Fig. 1;

Fig. 3 is a cross sectional view of the indwelling needle set shown in Fig. 1;

Fig. 4 is a cross sectional view of the indwelling needle set shown in Fig. 1 with the inner needle withdrawn from the outer needle and the needle tip protector device separated from the outer needle;

Fig. 5 is a cross sectional view illustrating the inner needle assembly of the indwelling needle set shown in Fig. 1 connected to a syringe;

Fig. 6 is a side view of the needle tip protector device of the indwelling needle set shown in Fig. 1;

Fig. 7 is a front view of the needle tip protector device shown in Fig. 6;

Fig. 8 is a backside view of the needle tip protector device shown in Fig. 6;

Fig. 9 is a cross sectional view of the needle tip protector body of the needle tip protector device shown in Fig. 6;

Fig. 10 is a cross sectional view along section lines 10–10 of Fig. 9;

Fig. 11 is a cross sectional view of the stopper member of the needle tip protector device shown in Fig. 6;

Fig. 12 is a front view of the stopper member shown in Fig. 11;

Fig. 13 is a cross sectional view illustrating the indwelling needle set shown in Fig. 1 with the needle tip protector device installed into the outer needle and with the inner needle positioned within the outer needle;

Fig. 14 is a cross sectional view of the outer needle assembly of the indwelling needle set after the needle tip protector device and the inner needle assembly have been removed positioned adjacent the connecting portion of a tube member; and

Fig. 15 is a cross sectional view of outer needle assembly of the indwelling needle set shown in Fig. 14 with the connecting portion of the tube member connected to the outer needle.

DETAILED DESCRIPTION

The needle tip protector device in accordance with the present disclosure will now be explained in detail with the reference to the drawings. Figs. 1 to 13 show an indwelling needle set A including one embodiment of the presently disclosed needle tip protector device 30. The indwelling needle set A comprises an outer needle assembly 10 to be positioned within a blood vessel of a patient (indwelling needle), an inner needle assembly 20 dimensioned to be inserted into the outer needle 10 and having a sharpened tip end portion configured to penetrate into the body of a patient, and the tip protector device 30. The outer needle assembly 10, as shown in Fig. 4, includes a narrow tube like cannula 11 and a housing 12 connected to the basal end portion (the rear portion positioned to the right side in Fig. 4) of the cannula 11.

The cannula 11 defines a lumen 11a (FIG. 3) which forms a flow path that extends from the tip end portion of cannula 11 to the rear end portion of cannula 11. In use, the tip end portion 11b of the cannula 11 is positioned within the blood vessel of a patient for removing blood from or supplying medicinal solutions or the like to a blood vessel. Also, the basal end portion of the cannula 11 is formed such that the diameter thereof gradually increases towards the rear end portion of cannula 11. The housing 12 defines a chamber and comprises a housing body 12a connected to the basal end portion of the cannula 11 and a housing tube 12b (FIG. 3) positioned within and along the rear end of the housing body 12a.

A front end portion of the housing body 12a is formed into a tapered cylinder in which the size thereof is gradually decreased from its rear end to its front end. The front end portion of housing body 12a is provided with an annular engagement groove 13a (FIG. 4) on its tip end portion for fixing the basal end portion of the cannula 11 to the front end of housing body 12a. The rear portion of the housing body 12a is formed into a cylinder having a diameter defining a space or cavity 13b. Space 13b includes a generally tapered front portion and a rear end having a generally constant diameter. The outer profile of the housing body 12a has a generally constant diameter portion and a slightly wider ring shaped projection 13c which is formed along the circumference at the rear end of the outer peripheral surface of the housing body 12a.

The housing tube 12b comprises an inner tube portion 14a provided within the housing body 12a which contacts the rear portion of the inner peripheral surface of the housing body 12a and a tube portion 14b which engages and extends rearwardly from the rear end of the housing body 12a. Also, an annular projection 14c is provided on the front end of the outer peripheral portion of the tube portion 14b. The annular projection 14c is configured so as to cover the outer peripheral surface of the rear end of the housing 12a. The housing tube 12b is connected to the housing body 12 by sandwiching the rear end portion of the housing body 12a between the basal end portion of the inner tube portion 14a and the projection 14c.

When housing tube 12b is attached to housing body 12a, the tip end portion of the projection 14c contacts the rear end portion of the projection 13c of the housing body 12a. An outer peripheral surface 14b of housing tube 12b includes a projection 14d and an external thread 14e. Projection 14d is located on the forward end of tube portion 14b and external thread 14e is located on the rear end of tube portion 14b. An inner peripheral surface 14f of the tube 12b has a tapered surface is gradually decreased in diameter from the rear end opening to the forward end opening. The diameter of an inner peripheral surface 14g of housing tube 12b is provided so as to be larger than the diameter of the inner peripheral surface 14f of housing tube 12b. Therefore, a differential step is formed between the inner peripheral surface 14g and the inner peripheral surface 14f.

A partition wall 15 is positioned at the forward end portion of the inner tube 14a in the inner peripheral surface 14g of the housing body 12a and a valve 16 is provided on the forward side of the partition wall 15 in the space 13b of the housing body 12a. A tube insertion portion 17 is provided within the housing tube 12b adjacent the rear side of the partition wall 15. The partition wall 15 is formed by a disc having a hole 15a at the center thereof for communicating the front portion of the space 13b with the rear portion of space 13b in the housing body 12a.

In one embodiment, the valve 16 is formed by an elastic isoprene rubber and comprises a chamber type valve including a pair of circular box bodies each having an opened surface opposed to the other. The valve 16 also includes an opening and closing hole 16a along the central axis of the valve 16. Through hole 16a, a predetermined narrow member can be inserted. When the narrow member is not inserted through hole 16a, because of the elastic properties of valve 15, the valve 16 is maintained in an occluding condition as shown in Fig. 3. On the other hand, when a puncturing needle 21 or the like as described below is inserted

through hole 16a, as shown in Fig. 3, the valve 16 tightly contacts the outer peripheral surface of the puncturing needle 21 or the like to provide a liquid tight seal about the puncturing needle 21.

The tube insertion portion 17 comprises a two stepped tube having an axial length almost the same as that of the housing tube 12b. The tube insertion portion 17 includes a basal portion 17a having a large diameter and an insertion end 17b extending forwardly from the front surface of the basal portion 17a having a smaller diameter. A spring receiving portion 17c of tube insertion portion 17 includes an annular projection. The annular projection is formed on the outer peripheral surface of the basal portion 17a of tube insertion portion 17. The spring receiving portion 17c is axially movably positioned within the inner peripheral surface 14g of the housing tube 12b and contacts the step portion defined between the inner peripheral surface 14g and the inner peripheral surface 14f, to prevent the portion 17c from moving beyond the inner peripheral surface 14f of tube 14b.

When the spring receiving portion 17c engages the step portion between the inner peripheral surface 14g and the inner peripheral surface 14f, the tip end portion of the insertion end 17b of tube insertion portion 17 is located within the hole 15a of the partition wall 15 and the basal portion 17a of tube insertion portion 17 is positioned near the rear end portion of the housing tube 12b. The insertion end 17b is dimensioned and configured such that it can be inserted into the hole 15a of partition wall 15 and passed through the hole 16a of the valve 16 in a liquid tight manner. When insertion end 17b is passed through the hole 16a of the valve 16, the inside of the tube insertion portion 17 communicates with the lumen 11a of the cannula 11 through the space 13b. A coil spring 18 is provided between the partition wall 15 and the spring receiving portion 17c of insertion portion 17 in the inner tube 14a so as to surround the outer periphery of the insertion end 17b of insertion portion 17 and the forward end of the basal portion 17a to urge the tube insertion portion 17 rearwardly. In its rearward position, tube insertion portion 17 is spaced rearwardly of valve 16.

The inner needle assembly 20, as shown in Fig. 5, comprises the puncturing needle 21 which can be made of stainless steel, and a hub 22 which is fixed to the basal end portion (rear end portion positioned to the right side in FIG. 5) of the puncturing needle 21. A syringe 23 is connected to the hub 22. The puncturing needle 21 includes a narrow tubular hypodermic needle having a sharp tip end portion 21b formed on the forward end of a puncturing portion 21a. Sharp tip end portion 21a is formed by providing an inclining or

tapering puncturing portion 21a. A step portion 21c (the engagement portion) is formed at the rear end portion of the puncturing portion 21a at a forward end of puncturing needle 21. In one embodiment, the diameter of the puncturing portion 21a, which is positioned forwardly of step portion 21c, is slightly larger than the diameter of a rear end portion, i.e., the portion of puncturing needle 21 positioned rearwardly of step portion 21c.

Sharp tip end portion 21b of the puncturing needle 21 is provided to facilitate smooth insertion of needle 21 and the tip end portion 11b of the cannula 11 into the blood vessel of the patient. Thus, the puncturing needle 21 is inserted into the outer needle 10 from the rear end portion of the outer needle 10 through the needle tip protector 30, as described below, such that the puncturing portion 21a of needle 21 projects outwardly from the opening of the tip end portion 11b of the cannula 11. When indwelling needle set A is assembled for use, the puncturing portion 21a of the puncturing needle 21 is passed through the inside of the needle tip protector 30, the inside of the tubular insertion portion 17, the hole 16a of the valve 16, the space 13b of the housing body 12a and the lumen 11a of the cannula 11 to project outwardly from the tip end portion 11b of the cannula 11.

The hub 22 of inner needle assembly 20 is configured as a holding portion for grasping the inner needle 20. Hub 22 can be formed from a transparent resin material which is fixed to the puncturing needle 21 so as to cover the outer periphery of the basal end portion of the puncturing needle 21. Hub 22 comprises a hub body 22a positioned at a central portion of hub 22 for fixing the puncturing needle 21 to hub body 22. Hub 22 also includes a flange shaped receiving portion 22b formed at a forward end of the hub body 22a which is dimensioned to maintain a predetermined distance between the periphery of the puncturing needle 21 and flange portion 22b, and a cylindrical female lure part 22c including a recess formed at the rear side of the hub body 22a. The syringe 23 is attached to the female lure part 22c of hub 22. The syringe 23 is comprised of a cylinder part 23a and a piston part 23b. The syringe 23 is connected to the inner needle assembly 20 by inserting a male lure part 23c formed at the tip end portion of the cylinder part 23a of syringe 23 into the female lure part 22c of hub 22.

The needle tip protector 30 shown in Figs. 6 to 8 releasably engages the outer periphery of tube portion 14b of housing 12. When needle set A is assembled, the puncturing needle 21 of the inner needle 20 is passed through the needle tip protector device 30 and extends to the tip end side of the cannula 11. The needle tip protector 30 comprises a protector

body 31 which is configured to be mounted to the tube portion 14b of housing 12. A needle tip protecting sleeve 32 is mounted to the protector body 31 and is movable forwardly and backwardly from a position extending into the protector body 31 to a position extending rearwardly from the protector body 31. A stopper member 33 FIGS. 11 and 12 is attached to the protector body 31 so as to be upwardly and downwardly moveable and a biasing member, e.g., a coil spring 34 is positioned to urge the stopper member 33 downwardly as illustrated in FIG. 4.

The protector body 31 includes a generally box shaped case member which is opened at it forward end. A rear wall of body 31 is provided with an engagement tube 35 which extends outwardly and backwardly from the rear wall. An upper side of protector body 31 is formed into almost a cylindrical shape (FIG. 10) which corresponds with the outer profile of the tube portion 14b to which protector body 31 is engaged. The lower side portion of protector body 31 includes a pair of substantially parallel, spaced wall portions. The engagement tube 35, as shown in Fig. 9, defines an engagement hole 35a having a diameter at its forward end(the portion positioned at the inside of the protector body 31) that is slightly larger than the diameter of engagement hole 35a at its rear end. A step is defined between the forward end and the rear end of hole 35a.

Protector body 31 includes a diaphragm 36 located towards the rear wall of protector body 31 for partitioning the upper side portion of the protector body 31 into a front portion and a rear portion. The rear portion of the protector body 31 forms a stopper member receiving portion 31a. The forward portion of protector body 31 forms a covering portion 31b for covering the tube portion 14b. The diaphragm 36 also includes an insertion hole 36a which opposes engagement tube 35 and has a diameter generally the same as the large diameter portion of the engagement hole 35a. Insertion hole 36a is provided so as to be coaxial with the engagement hole 35a.

The inner wall surface of the stopper member receiving portion 31a, as shown in Fig. 10, is formed so as to define a generally rectangular space within the stopper member receiving portion 31a. Guide holes 37a and 37b are formed through both sides of stopper member receiving portion 31a. A ceiling portion of the stopper member receiving portion 31a includes a circular projection hole 37c. The upper side portion of the inner wall surface of the covering portion 31b defines a generally cylindrical space and the lower side portion of the covering portion 31b defines a generally rectangular space.

The needle tip protecting sleeve 32 includes a cylindrical body having an axial length which is slightly longer than the length of the protector body 31. The diameter of tip protecting sleeve 32 is smaller towards the rear end of sleeve 32 such that the rear end of the sleeve 32 defines a narrow opening 32a. The diameter of opening 32a is large enough to slidably receive the rear end of puncturing needle 21 but to small to allow passage of puncturing portion 21a of puncturing needle 21. The forward end of sleeve 32 defines a larger diameter opening 32b through which the puncturing portion 21a of puncturing needle 21 can be inserted. The outer diameter of the forward end of sleeve 32 is larger than the diameter of the rear end of engagement hole 35a. The outer diameter of the rear end of sleeve 32 is smaller than the diameter of the rear end of engagement hold 35a. Thus, sleeve 32 can be slid within engagement hole 35a from a retracted extending rearwardly from protector body 31 to an advanced positioned substantially located within protector body 31 but can not be removed from the rear end of engagement hole 35a because the outer diameter of the forward end of sleeve 32 can not pass through engagement hole 35a.

When the puncturing needle 21 is positioned within sleeve 32 and slid forwardly, the puncturing portion 21a of puncturing needle 21 projects or extends from the forward end of needle tip protecting sleeve 32. In that condition, the portion 21a of needle 21 is movable forwardly and backwardly from the rear portion of the protector body 31 through the insertion hole 36a and the engagement hole 35a. When the needle tip protecting sleeve 32 is accommodated in the protector body 31 in its advanced position, the needle tip protecting sleeve 32 passes through the insertion hole 36a to position the narrow opening portion 32a within the engagement hole 35a. When the needle tip protecting sleeve 32 is in its retracted position projecting from the rear portion of the protector body 31, the large diameter opening 32b of the needle protecting sleeve 32 engages the step of the engagement hole 35a, thereby preventing sleeve 32 from being pulled through engagement hole 35a.

The stopper member 33 is disposed within the protector body 31 so as to be upwardly and downwardly moveable. As shown in Figs. 11 and 12, stopper member 33 includes a stopper body 33a and an engagement piece 33b. The stopper body 33a is disposed within the stopper member receiving portion 31a and the engagement piece 33b is positioned at a lower side portion of the covering portion 31b. The stopper body 33a is formed so as to be oblong and is provided with a frame body 38, having a square shaped stopper hole 38a formed

in a center portion thereof. The stopper hole 38a extends through the body 38 and is dimensioned to receive sleeve 32. The upper and the lower surfaces defining the stopper hole 38a are convex such that the distance between the central portions thereof is shorter than at the ends. As such, the contact resistance caused by the passing the needle tip protecting sleeve 32 through hole 38 is decreased.

The upper portion of the body 38 includes, a cylindrical engagement portion 38b which is movable in relation to and into engagement with projection hole 37c of the protector body 31. Guide projections 38c and 38d are provided on opposite sides of body 38. Guide projections 38c and 38d are slidably positioned within guide holes 37a and 37b of the protector body 31 to guide movement of body 38. A lower portion of the stopper body 33a has a U shape cross section with the open side of the U shape facing downwardly. An engagement piece 33b extends forwardly from a lower end front portion of body 38. Further, an engagement claw 39 projects upwardly from a forward end of engagement piece 33b. Engagement claw 39 is positioned to engage projection 14d which is positioned on the outer periphery of housing tube 12b.

The stopper member 33, as described above, can be installed to the protector body 31 by positioning the guide projections 38c and 38d within the guide holes 37a and 37b, respectively. As discussed above, engagement between projections 38c and 38d and guide holes 37a and 37b, guide the up and down movement of stop member 33. The coil spring 34, which may be formed of stainless steel, is mounted about engagement portion 38b between the upper surface of the frame body 38 of the stopper member 33 and the ceiling portion of the stopper member receiving portion 31a of the protector body 31. The diameter of the coil spring 34 is larger than that of the projection hole 37c, thereby preventing it from projecting from the projection hole 37c.

When the stopper member 33 is moved upwardly, the engagement portion 38b is positioned within the projection hole 37c as shown in Fig. 13 and the coil spring 34 is contracted or compressed by a force urging the stopper member 33 upwardly. When the force for urging the stopper member 33 upwardly is released, the coil spring 34 extends to move the stopper member 33 downwardly to the lower side of the protector body 31 as shown in Fig. 4. When the stopper member 33 is positioned in the lower side of protector body 31 and coil spring 34 is extended, guide projections 38c and 38d contact a lower end portion of guide holes 37a and 37b, respectively. In this position, the lower surface of the engagement piece 33b of

the stopper member 33 is positioned at the lower end portion of the protector body 31.

The needle tip protector 30 is installed or secured to the housing 12 when the stopper member 33 is in the upper side of protector body 31 and coil spring 34 is compressed. During installation, tube portion 14b of housing tube 12b is positioned within the covering potion 31b of protector body 31 and needle tip protector 30, with the inner needle 20 disposed in the needle tip protecting sleeve 32, is inserted through the insertion hole 36a and the engagement hole 35a. When inner needle 20 is inserted through holes 35a and 36a, the stopper member 33 is maintained in the upper side of protector body 21 by the needle tip protecting sleeve 32 which is positioned within the stopper hole 38a of the frame body 38. In this position, the engagement portion 38b of stopper member 33 is positioned within the projecting hole 37c of protector body 31.

In the installed condition, the engagement claw 39 of the stopper member 33 is engaged with the projection 14d of the tube portion 14b to fix or secure needle tip protector 30 to the housing 12. When the inner needle 20 is pressed against the needle tip protecting sleeve 32, the engagement tube 35 of the protector body 31 is positioned within the receiving portion 22b of the hub 22 and the puncturing portion 21a of the puncturing needle 21 projects from the tip end portion 11b of the cannula 11.

When indwelling needle set A is in its installed condition, the coil spring 18 is extended such that the tube insertion portion 17 is positioned towards the rear end of the housing 12 and the forward end of the needle tip protecting sleeve 32 is positioned within the basal portion 17a of the tube insertion portion 17. The outer needle 10, the inner needle 20 and the needle tip protector 30 are installed in this way to provide the indwelling needle set A shown in Figs. 1 to 3. In one embodiment, the cannula 11, the housing 12, the tube insertion portion 17, the protector body 31 and the stopper member 33 of the indwelling needle set A are formed from a resin material and the coil springs 18 and 34 and the needle tip protecting sleeve 32 are formed from a metallic material. Alternatively, other materials of construction are envisioned.

When using the indwelling needle set A, for example, to collect blood from the blood vessel of the patient, firstly, the tip end portion 11b of the cannula 11 together with the puncturing portion 21a of the puncturing needle 21 is inserted into the body of a patient to access a blood vessel. Then, the piston portion 23b of the syringe 23 is gradually pulled from or

retracted within the cylinder part 23a of syringe 23. As this occurs, blood in the blood vessel is drawn into the puncturing needle 21 and enters the hub body 22a of the hub 22 and, therefore cylinder part 23a of syringe 23. As a result, blood can be visualized in cylinder port 23a of syringe 23 and/or hub 22 to confirm that puncturing needle 21 has entered a blood vessel.

Next, with the tip end portion 11b of the outer needle 10 positioned in the blood vessel of the patient, the inner needle 20 together with the syringe 23 is retracted toward the rear end of the outer needle 10. When this occurs, the puncturing needle 21 is retracted from within the outer needle 10. It is noted that as the inner needle 20 is withdrawn from the outer needle 10, the puncturing end 21a of inner needle slidably contacts the peripheral surface of the hole 16a of the valve 16. As the puncturing needle 21 passes through the hole 16a of the valve 16, the puncturing needle 21 and the inner peripheral surface of the hole 16a are in sealing contact with each other. Thus, blood is prevented from leaking out of the hole 16a. After the puncturing needle 21 is pulled from outer needle 10, the hole 16a of valve 16 will close to prevent blood from leaking to the rear end of the housing 12.

When the inner needle 20 is pulled toward the rear end of the outer needle 10, the puncturing portion 21a of the puncturing needle 21 engages the narrow opening portion 32a of the needle protecting sleeve 32 to effect rearward movement of the needle tip protecting sleeve 32. As the needle tip protecting sleeve 32 is moved rearwardly and the large diameter opening portion 32b of sleeve 32 passes through the inserting hole 36a of the diaphragm 36 and the stopper hole 38a of the stopper member 33, the stopper member 33 is urged downwardly to a lower side of protector body 31 by the restoration force of the coil spring 34. When this occurs, engagement claw 39 is moved downwardly and is disengaged from projection 14d of the tube portion 14b. Accordingly, the needle tip protector 30 is disengaged from the outer needle 10 and is separated from outer needle 10 with the puncturing needle 21 attached thereto to provide the condition shown in Fig. 4.

When needle tip protector 30 and puncturing needle 21 are separated from outer needle 10, the large diameter opening portion 32b of the needle tip protecting sleeve 32 is engaged with the step of the engagement hole 35a and the needle tip protecting sleeve 32 projects outwardly from the rear end of the protector body 31. In this position, the puncturing needle 21 cannot be pulled from the rear end of engagement tube 35 of protector body 31 because the puncturing portion 21a of the puncturing needle 21 is too large to pass through the narrow diameter opening portion 32a of the needle tip protecting sleeve 32. The puncturing

needle 21 also cannot be advanced forwardly from protector body 31 because the stopper member 33 is positioned in front of the large diameter opening portion 32b of the needle tip protecting sleeve 32. Therefore, after use, access to puncturing portion 21a of needle 21 is prevented and the inner needle 20 and needle tip protector 30 can be disposed of in a safe manner.

Referring to FIGS. 4 and 14, after inner needle 20 and needle tip protector 30 have been separated from outer needle 10, the housing 12 of the outer needle 10 is connected to a tube member 42 (see Fig. 14) to supply a medicinal solution or the like to a patient. To accomplish this, a connecting portion 43 secured to the tip end of the tube member 42 is connected to the tube portion 14b of the housing 12 such that a forward end of the connecting portion 43 is received within the basal portion 17a of the tube insertion portion 17 as shown in Fig. 14. The connecting portion 43 includes a connecting portion body 44 which is fixed to the tip end portion of the tube member 42 and a cap like tube connecting portion 45 which is rotatably supported about the axis of the connecting portion body 44.

The connecting portion body 44 includes a fixing portion 44a which is fixed to the outer periphery of the tip end of the tube member 42, and a tapered male lure part 44b that can be inserted into the tube portion 14b to tightly contact an inner peripheral surface 14f of housing tube 12b. Connecting portion 45 has an internal thread 45a that is capable of being engaged with the external thread 14e of the housing 12. Engagement of internal thread 45a and external thread 14e draws the male lure part 44b into the tube portion 14b to connect the outer needle 10 to tube member 42 as shown in Fig. 15.

When the connecting portion 43 is connected to the outer needle 10, the male lure part 44b engages the rear end of the tube insertion portion 17 to move tube insertion portion 17 forwardly against the elasticity of the coil spring 18. As tube insertion portion 17 moves forwardly, the insertion end 17b of the tip end side of the tube insertion portion 17 penetrates the hole 16a of the valve 16. When insertion end 17b of tube insertion portion 17 penetrates hole 16a of valve 16, a lumen defined by tube insertion portion 17 fluidly communicates with the lumen 11a of the cannula 11 through the space 13b of the housing body 12a. Accordingly, a feeder (not shown), e.g., an IV bottle, for medicinal solution or the like which is connected to the basal end portion of the tube member 42 can supply fluid to cannula 11 when the connecting portion 43 is secured to the outer needle 10 to supply fluid to a blood vessel.

As discussed above, the needle tip protector 30 in accordance with this embodiment of the disclosure includes the protector body 31 and the needle tip protecting sleeve 32. The needle tip protecting sleeve 32 is movable forwardly and backwardly between an advanced position located inside of the protector body 31 and a retracted position in which the sleeve 32 projects rearwardly through the engagement hole 35a of the engagement tube 35 of the protector body 31. Further, the forward puncturing portion 21a of the puncturing needle 21 is formed so as to have a greater diameter than the rear portion of the puncturing needle 21 such that the rear portion of the puncturing needle 21 can be inserted through the needle tip protecting sleeve 32, but the forward puncturing portion 21a of the needle 21 cannot pass through the narrow diameter opening portion 32a of protective sleeve 32.

In summary, the tip end portion 11b of the cannula 11 and the puncturing portion 21a of the puncturing needle 21 of the indwelling needle set A, are inserted into the body of the patient. Thereafter, the outer needle 10 is retracted in relation to the inner needle 20 to separate the inner needle 20 from the outer needle 10. The inner needle 20 is withdrawn through engagement hole 35a of tip protector 30 such that the puncturing portion 21a of needle 21 engages the narrow diameter opening 32a of the needle tip protecting sleeve 32. When this occurs, the needle tip protecting sleeve 32, while it covers the puncturing portion 21a, is withdrawn through hole 35a of the protector body 31. When the needle tip protecting sleeve 32 is withdrawn through the stopper hole 38a of the stopper member 33, the needle tip protecting sleeve 32 is disengaged from the stopper member 33. Therefore, the stopper member 33 is moved by the coil spring 34 to the position where it covers the engagement hole 35a.

Because, as discussed above, the puncturing portion 21a of the puncturing needle 21 can not be retracted from the narrow diameter opening portion 32a or advanced into the protector body 31, the puncturing portion 21a of needle 21 can be maintained in a safe condition where it is covered by the needle tip protector 30. Therefore, inner needle assembly 20 and needle tip protector 30 can be safely discarded. Moreover, when the needle tip protector 30 is installed onto the indwelling needle set A, the needle tip protecting sleeve 32 is positioned within the protector body 31. Thus, the length of the indwelling needle set A has not been increased by the length of such a sleeve. Accordingly, the operativity of the indwelling needle set A need not be decreased.

The projection 14d is provided on the housing 12 and the engagement piece 33b including the engagement claw 39 is provided on the stopper member 33. The engagement claw 39 is engaged with the projection 14d when the needle tip protecting sleeve 32 is positioned within the stopper hole 38a of the stopper member 33. In turn, the engagement of the engagement claw 39 with the projection 14d is released when the needle tip protecting sleeve 32 is withdrawn from the stopper hole 38a. When the inner needle 20 is withdrawn from the outer needle 10, the needle tip protecting sleeve 32 mounts to the puncturing portion 21a of the puncturing needle 21 and separation of sleeve 32 and needle 21 is prevented. Further, the needle tip protector 30 can be detached from the outer needle 10 together with the inner needle 20. Therefore, the attachment of the needle tip protecting sleeve 32 to the puncturing portion 21a and the detachment of the needle tip protector 30 from the outer needle 10 can be performed only by the operation of withdrawing the inner needle 20 from the outer needle 10.

The needle tip protector in accordance with the disclosure is not intended to be limited to the embodiments described above, i.e., various modifications can be made thereto by those of ordinary skill in the art. For example, in the above described embodiment, though the indwelling needle set including the needle tip protector is inserted into a blood vessel, the indwelling needle set including the needle tip protector in accordance with the present disclosure may be applied not only to blood vessels but also to sites in the body such as the intestine, for example, duodenum; pyelitis; or urinary bladder.

Although the protector sleeve is described as having a stepped portion and a narrow diameter portion for engaging the puncturing portion of the needle, other configurations may be provided so long as the engagement portion and the engagement opening portion can be engaged with each other. For example, a needle having a constant outer diameter and a projection formed at the tip end portion of the needle may be provided in combination with a sleeve having a portion capable of being engaged with that projection. In this case, the projection included in the puncturing needle may be in the form a ring like projection along the circumference of the needle, a projection formed at one position on the circumference of the needle, or a plurality of projections formed at a plurality of positions about the circumference of the needle.

Alternatively, a needle having a constant outer diameter and a recess provided at the tip end portion can be provided as the puncturing needle for use in association with a portion on the sleeve capable of being engaged with the recess. According to this embodiment, the puncturing needle can be engaged with the needle tip protecting sleeve when the projections and the like are engaged with the recess. Further, the recess included in the puncturing needle in this case may be in any form such as a ring like recess along the circumference of the needle, a recess formed at one position on the circumference of the needle, or a plurality of recesses formed at a plurality of positions on the needle.

WHAT IS CLAIMED IS:

1. A needle tip protection device comprising:

a needle tip protector body having a front portion configured to receive the rear end of an outer needle and a rear portion defining a rearwardly extending engagement tube defining a hole;

a stopper member supported within the rear portion of the needle tip protector body, the stopper member being movable from a first position obstructing the hole of the engagement tube to a second position providing access to the hole of the engagement tube; and

a protecting sleeve slidably positioned within the hole of the engagement tube between a first advanced position located substantially within the needle tip protector body and a retracted position extending rearwardly from the needle tip protector body through the hole of the engagement tube, the protecting sleeve having a forward end and a rear end, the rear end of the protecting sleeve being dimensioned to be slidably received in the hole of the engagement tube and the forward end of the protecting sleeve being dimensioned to prevent passage of the forward end of the protecting sleeve through the hole of the engagement tube,

wherein the protecting sleeve defines a bore having a forward opening having a first diameter and a rear opening having a second diameter smaller than the first diameter.

2. The needle tip protection device according to Claim 1, wherein the stopper member defines a hole, the hole in the stopper member being aligned with the hole in the engagement tube when the stopper member is in its second position and misaligned with the hole in the engagement tube when the stopper member is in its first position, the hole in the stopper member being dimensioned to permit passage of the protector sleeve.

3. The needle tip protection device according to Claim 2, wherein the stopper member is urged to its first position by a spring.

4. The needle tip protection device according to Claim 2, wherein the needle tip protector body further includes a diaphragm separating the front portion of the needle tip protector body and the rear portion of the needle tip protector body, the diaphragm defining an insertion hole which is aligned with the hole in the engagement tube.

5. The needle tip protection device according to Claim 1, wherein the stopper member includes an engagement piece configured to secure the needle tip protector body to a

needle housing of an indwelling needle set when the stopper member is in the second position.

6. The needle tip protection device according to Claim 5, wherein the engagement piece of the stopper member includes an engagement claw.

7. The needle tip protection device according to Claim 3, wherein the protecting sleeve extends through the hole in the stopper member when the protecting sleeve is in the advanced position, the protecting sleeve engaging walls of the sleeve defining the hole in the stopper member to retain the stopper member in its second position.

8. The needle tip protection device according to Claim 7, wherein the walls of the sleeve defining the hole in the stopper member are convex.

9. The needle tip protection device according to Claim 1, wherein the hole in the engagement tube defines a stepped bore, a rear portion of the stepped bore having a diameter which is smaller than a diameter of a forward portion of the stepped bore.

10. The needle tip protection device according to Claim 9, wherein a step is defined between the forward portion of the stepped bore and the rear portion of the stepped bore, the forward end of the protecting sleeve engaging the step when the protecting sleeve is in its retracted position.

11. An indwelling needle set comprising:

an outer needle including a cannula and a housing body defining a chamber;

an elastic valve supported within the chamber;

an inner needle having a forward puncturing end and a rear end, the forward puncturing end having an enlarged diameter portion; and

a needle tip protection device including:

i) a needle tip protector body having a front portion configured to receive the rear end of the housing of the outer needle and a rear portion defining a rearwardly extending engagement tube defining a hole;

ii) a stopper member supported within the rear portion of the needle tip protector body, the stopper member being movable from a first position obstructing the hole of the engagement tube to a second position providing access to the hole of the engagement tube; and

iii) a protecting sleeve slidably positioned within the hole of the engagement tube between a first advanced position located substantially within the needle tip protector body and a retracted position extending rearwardly from the needle tip protector body through the hole of the engagement tube, the protecting sleeve having a forward end and a rear end, the rear end of the protecting sleeve being dimensioned to be slidably received in the hole of the engagement tube and the forward end of the protecting sleeve being dimensioned to prevent passage of the forward end of the protecting sleeve through the hole of the engagement tube,

wherein the protecting sleeve defines a bore having a forward opening having a first diameter and a rear opening having a second diameter smaller than the first diameter, the inner needle being slidably positioned within the protecting sleeve, the enlarged diameter portion of the inner needle being greater in diameter than the second diameter of the rear opening of the protecting sleeve.

12. The indwelling needle set according to Claim 11, further including a tube insertion portion movably supported within the housing, the tube insertion portion defining a bore and being movable from a rearward position to a forward position, an insertion end of the tube insertion portion extending through an opening in the elastic valve.

13. The indwelling needle set according to Claim 12, wherein the tube insertion portion is urged towards its rearward position by a spring.

14. The indwelling needle set according to Claim 11, wherein the housing body includes an external thread adapted to engage a tube member for supplying medicinal fluid to the needle set.

15. The indwelling needle set according to Claim 11, wherein the inner needle includes a hub member supported on a rear end of the inner needle.

16. The indwelling needle set according to Claim 11, wherein the stopper member defines a hole, the hole in the stopper member being aligned with the hole in the engagement tube when the stopper member is in its second position and misaligned with the hole in the engagement tube when the stopper member is in its first position, the hole in the stopper member being dimensioned to permit passage of the protector sleeve.

17. The indwelling needle set according to Claim 16, wherein the stopper member is urged to its first position by a coil spring.

18. The indwelling needle set according to Claim 16, wherein the needle tip protector body further includes a diaphragm separating the front portion of the needle tip protector body and the rear portion of the needle tip protector body, the diaphragm defining an insertion hole which is aligned with the hole in the engagement tube.

19. The indwelling needle set according to Claim 11, wherein the stopper member includes an engagement piece configured to secure the needle tip protector body to the housing body of the outer needle when the stopper member is in the second position.

20. The indwelling needle set according to Claim 19, wherein the engagement piece of the stopper member includes an engagement claw and the housing body of the outer needle includes a projection, the engagement claw being positioned to engage the projection when the stopper member is in its second position to secure the needle tip protector body to the housing body and to disengage the projection when the stopper member is in its first position to detach the needle tip protector body from the housing body.

21. The indwelling needle set according to Claim 17, wherein the protecting sleeve extends through the hole in the stopper member when the protecting sleeve is in the advanced position, the protecting sleeve engaging walls of the sleeve defining the hole in the stopper member to retain the stopper member in its second position.

22. The indwelling needle set according to claim 21, wherein the walls of the sleeve defining the hole in the stopper member are convex.

23. The indwelling needle set according to Claim 11, wherein the hole in the engagement tube defines a stepped bore, a rear portion of the stepped bore having a diameter which is smaller than a diameter of a forward portion of the stepped bore.

24. The indwelling needle set according to Claim 23, wherein a step is defined between the forward portion of the stepped bore and the rear portion of the stepped bore, the forward end of the protecting sleeve engaging the step when the protecting sleeve is in its retracted position.

REPLACEMENT SHEET

1/10

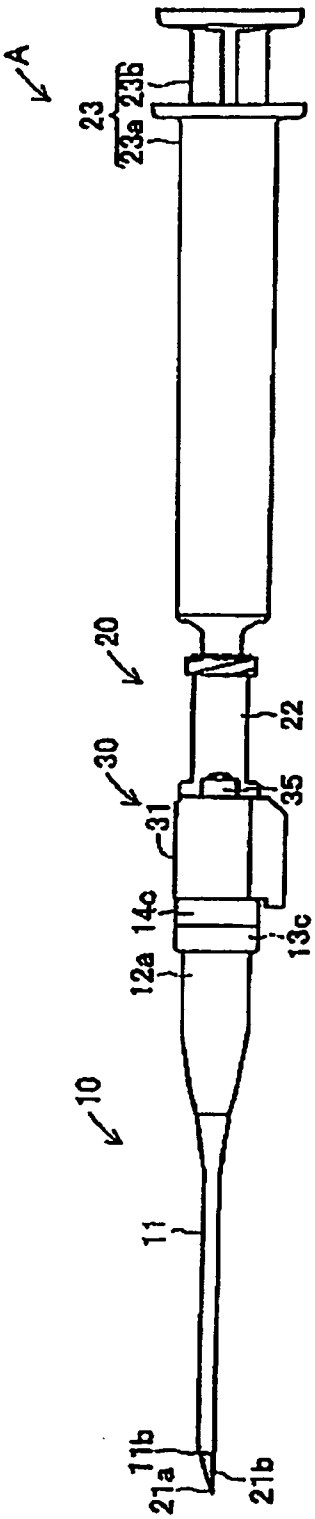

Fig. 1

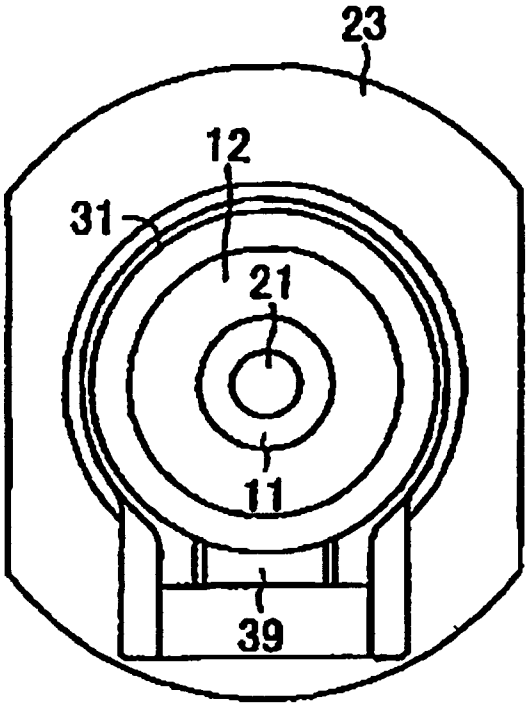

Fig. 2

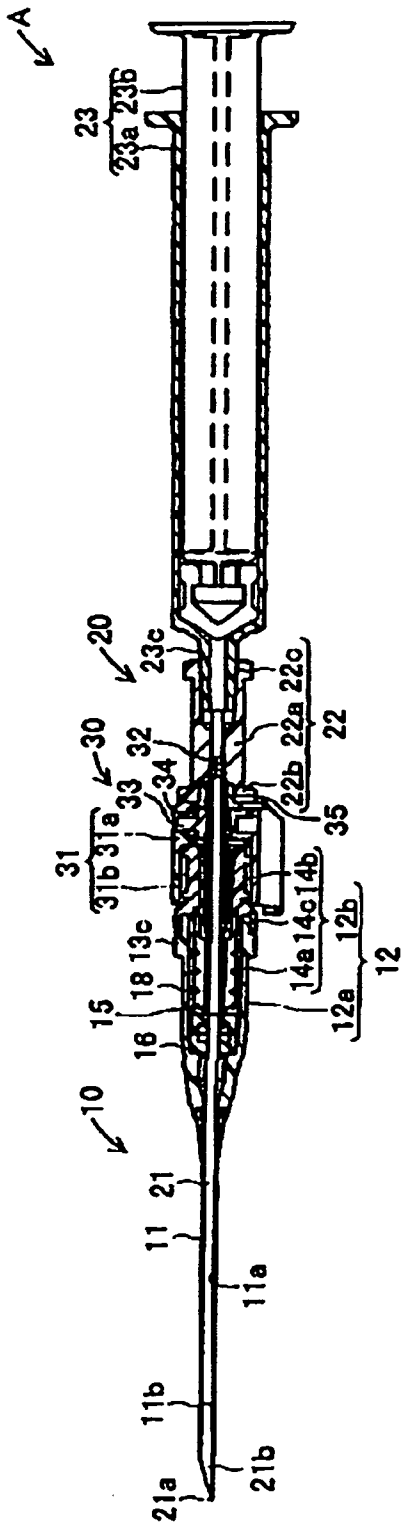
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Fig. 3

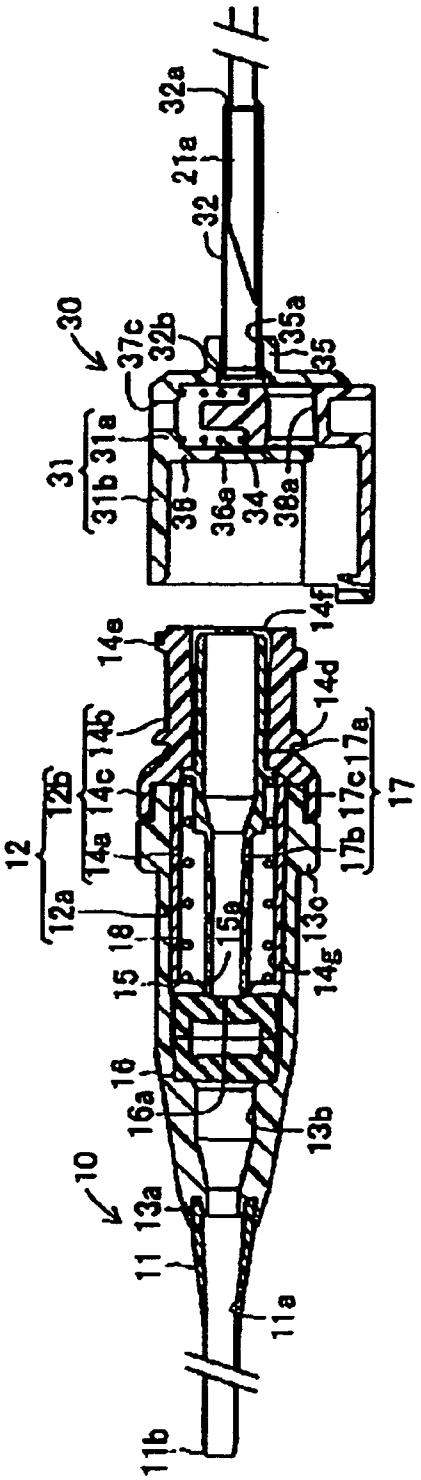
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Fig. 4

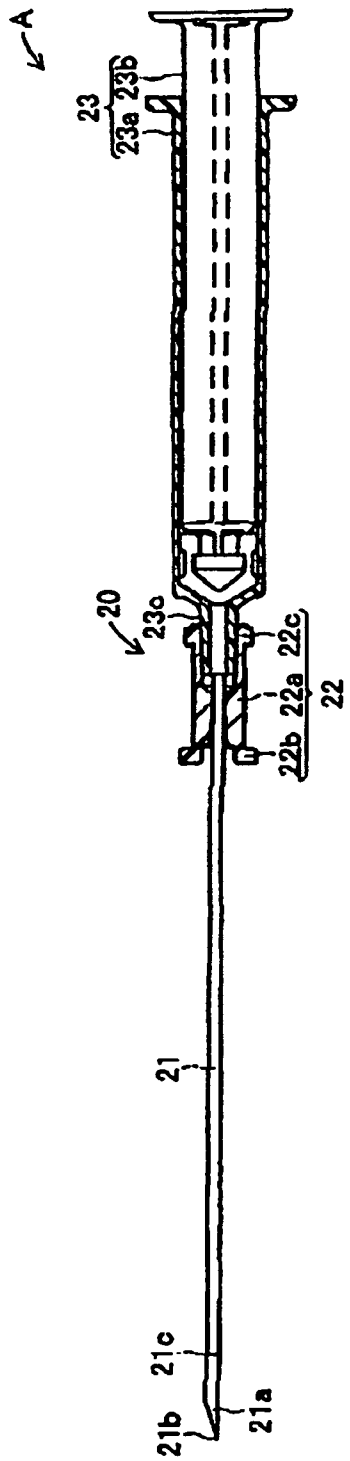

Fig. 5

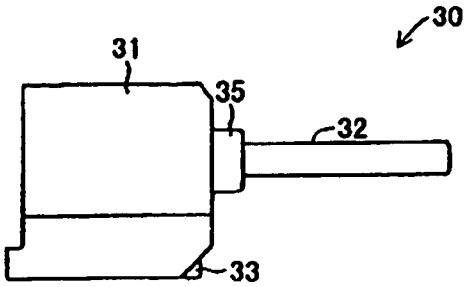

Fig. 6

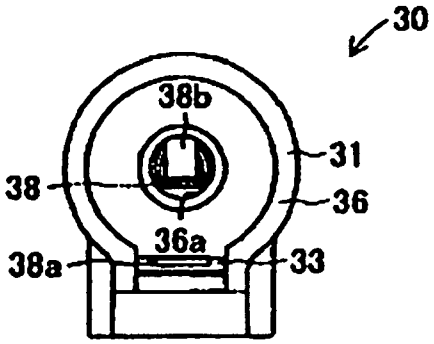

Fig. 7

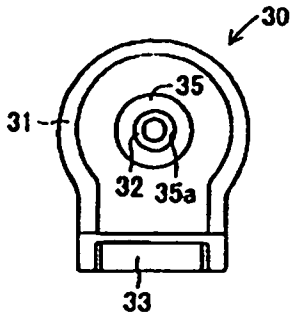

Fig. 8

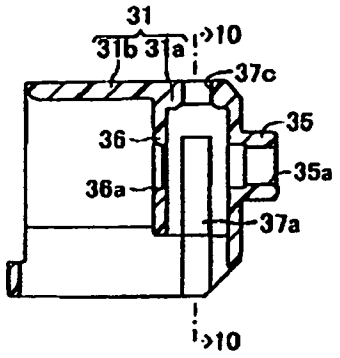

Fig. 9

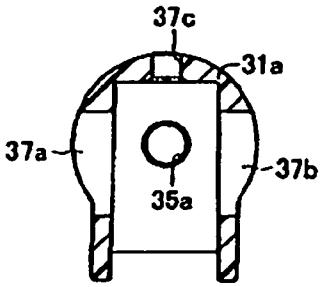

Fig. 10

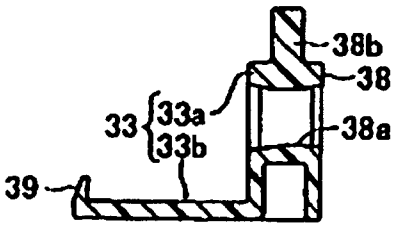

Fig. 11

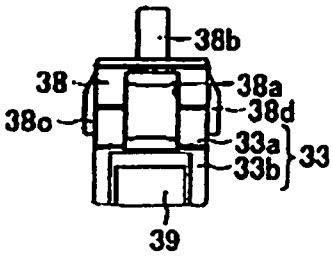

Fig. 12

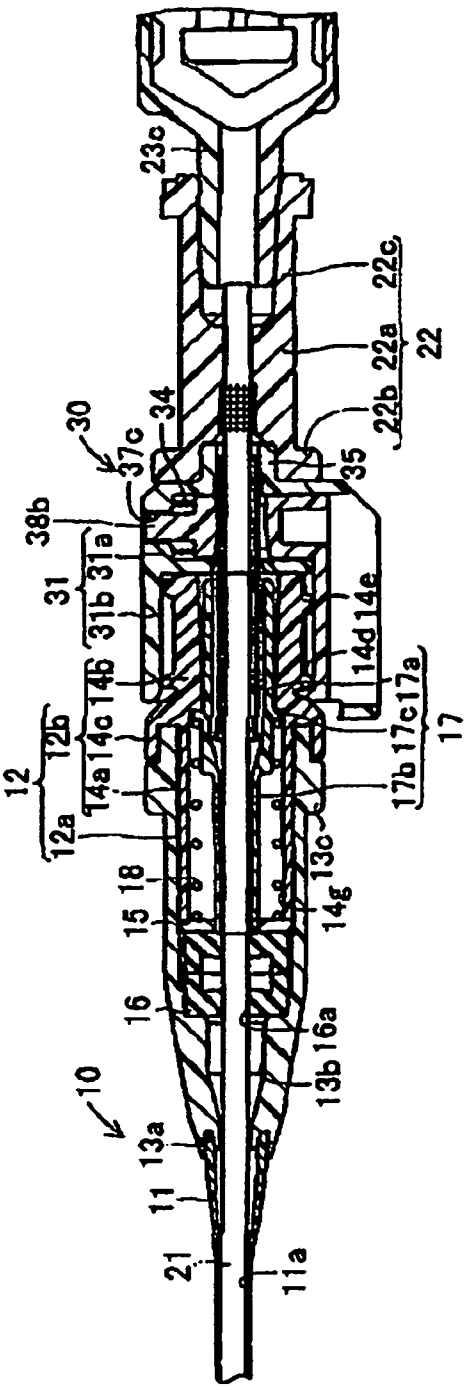
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Fig. 13

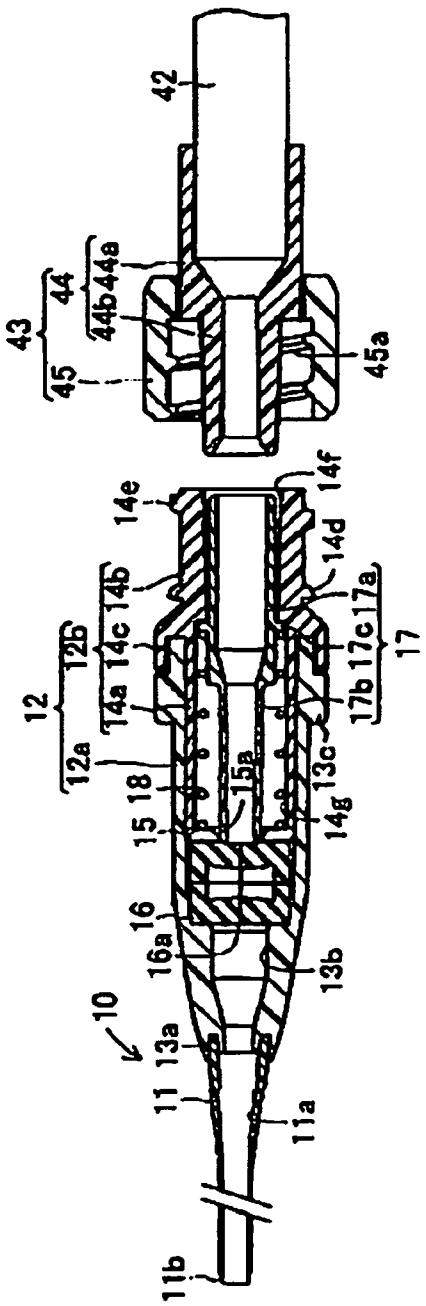
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Fig. 14

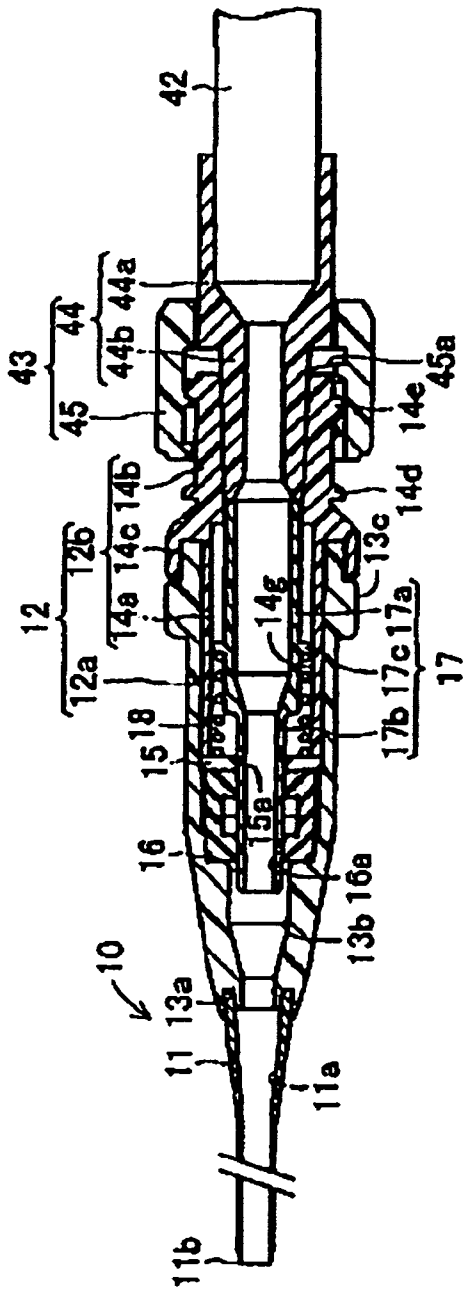
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Fig. 15