CATHETER AND INTRODUCER NEEDLE ASSEMBLY WITH SAFETY DEVICE

Technical Field

The present invention relates to a catheter and introducer needle assembly, and more specifically relates to a safety device for a catheter and introducer needle assembly.

Back Ground of the Invention

Intravascular Catheters, particularly intravenous (IV) catheters, are used for infusing fluid, such as normal saline solution, various medicaments and total parenteral nutrition, into a patient or withdrawing blood from a patient. Peripheral IV catheters tend to be relatively short, and typically are on the order of about two inches or less in length. The most common type of IV catheter is an over the needle peripheral IV catheter. As its name implies, an over the needle catheters is mounted over an introducer needle having a sharp distal tip. The catheter and the introducer needle are assembled so that the distal tip of the introducer needle extends beyond the distal tip of the catheter with the bevel of the needle facing up away from the patient.

The catheter and introducer needle assembly is inserted at a shallow angle through the patient's skin into a peripheral blood vessel, i.e a smaller blood vessel that is not connected directly to the heart but is one of the branches of the central blood vessels that is directly connected to the heart. In one technique, the introducer needle and catheter are inserted completely into the blood vessel together. In another technique, the introducer needle is partially withdrawn into the catheter after the initial venipuncture. The catheter is then inserted completely into the blood vessel.

After the assembly is inserted into the blood vessel, it is important to verify proper placement of the assembly in the blood vessel. In order to verify proper placement of the assembly in the blood vessel, the clinician confirms that there is flash back of blood in the needle and in a flashback chamber located at the proximal end of the needle. The flashback

chamber is typically formed as part of the needle hub. Alternatively, the introducer needle could include a flashback notch or opening formed along a distal portion thereof so that the blood flashback can be observed in the annular space between the introducer needle and the catheter when the catheter is transparent or at least translucent. Once proper placement is confirmed, the clinician applies pressure to the blood vessel by pressing down on the patient's skin over the distal tip of the introducer needle and the catheter. This finger pressure occludes further blood flow through the introducer needle. Occlusion of blood flow can also be achieved through a septum. The clinician withdraws the introducer needle, leaving the catheter in place, and attaches a fluid delivery device, a PRN or a dead ender cap to the catheter. Once the introducer needle is withdrawn from the catheter, it is a "blood contaminated sharp" and must be properly handled.

In recent years, there has been great concern over the contamination of clinicians with a patient' blood and a recognition that "blood contaminated sharps" must be immediately disposed. This concern has arisen because of the advent of currently incurable and fatal diseases, such as Acquired Immunosuppressive Deficiency Syndrome ("AIDS"), which can be transmitted by the exchange of body fluids from an infected person to another person. Thus, contact with the body fluid of an AIDS infected person must be avoided. As noted above, if an introducer needle has been used to place a catheter in the vein of an AIDS infected person, the introducer needle is a vehicle for the transmission of the disease. Although clinicians are aware of the need to properly handle "blood contaminated sharps", unfortunately in certain medical environments, such as emergency situations or as a result of inattention or neglect, needle sticks with a contaminated introducer needle still occur.

In order to solve the problem of accidental needle sticks by "blood contaminated sharps", various needle safety devices have been developed.

US6287278 discloses IV catheters including a spring clip for protecting the user. However, the IV catheters do not have a shield or a shield enclose the spring clip. Although the spring clip could protect the user

from contacting the needle tip, it could not protect the user from contacting the remnant blood found on the needle tip, especially when there are some periphery orifices found on the needle, such as the flashback notch. Therefore, the IV catheters of US6287278 are still somewhat unsafe to the user.

US5215528 discloses a catheter introducer assembly including a metal clip for protecting the user against needle sticks once the catheter is inserted into a blood vessel and the introducer needle is removed from the catheter. As show in the drawings of US5215528, the catheter introducer assembly includes a plurality of arcuate projections 50 extending from the flange 48, and the arcuate projections define a receptacle 53 for retaining a catheter adapter 52. One end of the tubular body 38 defines a nose portion 38a for extending within the catheter adapter. The ends of the projections include inwardly projecting lips 54 for releasably retaining the flange 56 of the catheter adapter. Arcuate projections 50 and lips 54 should be designed to engage flange 56 so that it is easier to push the tip cover away from the needle hub by means of tab 48b than it is to remove catheter adapter 52 from receptacle 53. However, the above engagement relationships are not reliable as it depends on the manufacturing tolerances. As such, the disengagement between the catheter adapter and the needle tip cover is not predictable and could happen even before the needle tip is safely protected. This erratic behavior is not suitable in an environment that requires accuracy and dependability.

US6749588 discloses a catheter and introducer needle assembly with a needle shield. The needle shield has a spring clip provided in. After the withdrawal of the introducer needle, the needle shield with the spring clip will hold on the introducer needle tip and prevent the user from contacting with the blood. However, such needle shield could not prevent reuse after its use, i.e. after the withdrawal of the introducer needle, the introducer needle could reinsert the catheter by pulling out of the spring clip from the needle shield without it being broken.

Therefore, it is still needed to improve the safety device for a catheter and introducer needle assembly so as to overcome the above-mentioned disadvantages.

Summary of the Invention

One object of the present invention is to provide a safety device for a catheter and introducer needle assembly which could not only protect the user from contacting the needle tip but also from any needle sticks found on the tip once the catheter is inserted into a blood vessel and the introducer needle is removed from the catheter.

Another object of the invention is to provide a safety device for a catheter and introducer needle assembly which could prevent reuse of the needle shield or the needle or the assembly after the withdrawal of the introducer needle, i.e. the user could not reset the spring clip to the original compressed mode after the withdrawal of the introducer needle.

The objects of the invention are achieved by a safety device for a catheter and introducer needle assembly, said catheter and introducer needle assembly comprising: a catheter assembly including: a catheter having a proximal end and a distal end; a catheter hub in fluid communication with the catheter and having a proximal end and a distal end connected to the proximal end of the catheter; an introducer needle assembly including: an introducer needle having a proximal end and a distal end and a longitudinally axis, and an needle hub affixed to the proximal end of the introducer needle, said introducer needle disposed in the catheter; and said safety device, said safety device including:

> a needle shield defining a longitudinally extending passage with an opening along the longitudinal direction of the longitudinally extending passage, the diameter of which is at least slightly larger than the diameter of the main portion of the introducer needle so as to allow the introducer needle to pass through the extending passage, said needle shield having at least one first latch and at least one second latch formed thereon;

a spring clip having at least one first catch, at least one second catch and a tab, said spring clip fitted into the needle shield through the opening, and the second catch of the spring clip is irreversibly engaged the second latch of the needle shield, and said spring clip is adapted to flex between a compressed mode prior to the withdrawal of the introducer needle and an uncompressed mode after the withdrawal of the introducer needle in a plane substantially perpendicular to the longitudinal axis of the introducer needle; and

a restriction means for restricting the distal end of the introducer needle from moving out of the needle shield after the withdrawal of the introducer needle.

Wherein, the spring clip is abutted in the compressed mode by the introducer needle passing through the extending passage and the second catch of the spring clip is irreversibly engaged to the second latch prior to the withdrawal of the introducer needle. Upon withdrawal of the introducer needle, the introducer needle moves past the spring clip, the spring clip is released by the introducer needle and sprung open into the uncompressed mode, and after the withdrawal of the introducer needle, the first catch of the spring clip is irreversibly engaged to the first latch of the needle shield, and the tab moves in front of the distal end of the introducer needle and prevents the distal end of the introducer needle from moving out of the shield distally after withdrawal of the introducer needle. The engagement between the first catch and the first latch prevents the spring clip from being recompressed after the withdrawal of the introducer needle and the engagement between the second catch and the second latch prevents the spring clip from being pulled out of the needle shield before and after the withdrawal of the introducer needle, and the restriction means restricts the distal end of the introducer needle from moving out of the needle shield proximally after the withdrawal of the introducer needle.

The present invention also provides a catheter and introducer needle assembly, said catheter and introducer needle assembly comprising:

a catheter assembly including: a catheter having a proximal end and a distal end; a catheter hub in fluid communication with the catheter and having a proximal end and a distal end connected to the proximal end of the catheter;

an introducer needle assembly including: an introducer needle having a proximal end and a distal end and a longitudinally axis, and an needle hub affixed to the proximal end of the introducer needle, said introducer needle disposed in the catheter; and

a safety device, including:

a needle shield defining a longitudinally extending passage with an opening along the longitudinal direction of the longitudinally extending passage, the diameter of which is at least slightly larger than the diameter of the shaft portion of the introducer needle so as to allow the introducer needle to pass through the extending passage, said needle shield having at least one first latch and at least one second latch formed thereon;

a spring clip having at least one first catch, at least one second catch and a tab, said spring clip fitted into the needle shield through the opening, and the second catch of the spring clip is irreversibly engaged the second latch of the needle shield, said spring clip is adapted to flex between a compressed mode prior to the withdrawal of the introducer needle and an uncompressed mode after the withdrawal of the introducer needle in a plane substantially perpendicular to the longitudinal axis of the introducer needle; and

a restriction means for restricting the distal end of the introducer needle from moving out of the needle shield after the withdrawal of the introducer needle.

Wherein, the spring clip is abutted in the compressed mode by the introducer needle passing through the extending passage and the second catch of the spring clip is irreversibly engaged to the second latch prior to the withdrawal of the introducer needle. Upon withdrawal of the introducer needle, the introducer needle moves past the spring clip, the spring clip is released by the introducer needle and sprung open into the uncompressed mode, and after the withdrawal of the introducer needle, the first catch of the spring clip is irreversibly engaged to the first latch of the needle shield, and the tab moves in front of the distal end of the introducer needle and prevents the distal end of the introducer needle from moving out of the shield distally after withdrawal of the introducer needle. The engagement between the first catch and the first latch prevents the spring clip from being recompressed after the withdrawal of the introducer needle and the engagement between the second catch and the second latch prevents the spring clip from being pulled out of the needle shield before and after the withdrawal of the introducer needle, and the restriction means restricts the distal end of the introducer needle from moving out of the needle shield proximally after the withdrawal of the introducer needle.

The present and further advantages of the invention will be apparent after reading the following description with reference to the following drawings which illustrate the preferred embodiments of the present invention.

Brief Description of the Drawings

The present invention will be described with reference to the

accompanying drawings in which the preferred embodiments of the invention are illustrated.

FIG 1 shows the complete product of the catheter and introducer needle assembly with the safety device enclosed within;

Fig 2 is an exploded view of the catheter and introducer needle assembly showed in Fig 1;

Fig 3 shows the spring clip of the first embodiment in large scale;

Fig 4 is a partial view of the catheter and introducer needle assembly of the first embodiment, which shows the state prior to the spring clip activation, and in this state, the spring clip folds back into compressed mode and held in compressed mode by the introducer needle.

Fig 5 is an alternate partial view of catheter and introducer needle assembly of the first embodiment, which shows the state prior to the spring clip activation;

Fig 6 is a perspective view which shows the position of the first catch of the spring clip in the needle shield prior to clip activation.

Fig 7 is an alternate view of the safety device of the first embodiment, which shows the state prior to clip activation ;

Fig 8 is a partial view of the catheter and introducer needle assembly of the first embodiment, which shows the state after clip activation.

Fig. 9 is an alternate view of catheter and introducer needle assembly of the first embodiment, which shows the state after clip activation.

Fig. 10 is an alternate view of catheter and introducer needle assembly of

the first embodiment, which shows the state after clip activation.

Fig. 11 is a perspective view, which shows position of the first catch of the spring clip in the needle shield after activation.

Fig. 12 is a section view, which shows the state of the needle tip with respect to the spring clip tab after activation.

Fig. 13 is a view in which the washer stops the introducer needle in aft direction movement.

Fig. 14 is a view which clearly shows the second catch engages the latch on the needle shield for reuse prevention purposes.

Fig. 15 is an exploded view which shows the second embodiment of the safety device including a V shaped spring clip;

Fig. 16 shows the V shaped spring clip in the second embodiment;

Fig. 17 shows the state of the safety device of the second embodiment after the clip activation;

Fig. 18 shows a washer which is used in the second embodiment.

Fig. 19 shows the third embodiment of the safety device which use a tether as the restriction means.

Preferred Embodiments of the Invention

As used herein, the term "proximal" and "distal" refer to a location on the catheter and introducer needle assembly with respect to introducer needle hub 34. The term "the fore direction" refers to the direction toward the introducer needle tip, and the term "the aft direction" refers to the direction away from the introducer needle tip.

The invention is described herein using like reference numbers for like elements in the different embodiments. In addition, while this invention is satisfied by embodiments in many different forms, there are shown in the drawings and herein described in detail, preferred embodiments of the invention with the scope of the invention measured by the appended claims.

Fig. 1-14 shows first embodiment of the present invention.

As shown in Fig. 1 and 2, a catheter and introducer needle assembly with safety device of the first embodiment of this invention is identified generally by the numeral 10. It includes a catheter assembly 20, an introducer needle assembly 30 and a safety device.

Catheter assembly 20 includes a catheter 21 that has a proximal end, a distal end, and a catheter hub 24 affixed to the proximal end of catheter 21. Suitable materials for catheter 21 include, but are not limited to, thermoplastic resins such as polytetrafluoroethylene (PTFE), polyurethane and the like. Preferably, catheter 21 is formed from transparent material or at least translucent so as to observe the flashback from an optional flashback notch 35 on the introducer needle 31. Suitable materials for catheter hub 24 include, but are not limited to, thermoplastic polymeric resins such as polycarbonate, polystyrene, polypropylene and the like.

Introducer needle assembly 30 includes introducer needle 31 having a sharp distal tip 32 defined by bevel and a proximal end connected to needle hub 34. Near the sharp distal tip 32, the introducer needle 31 includes a discontinuous portion 33 , such as an enlarged discontinuous portion in this embodiment . Introducer needle 31 is preferably formed from stainless steel. Optionally, a flashback notch 35 may be provided on the introducer needle 31 so as to observe the

flashback blood in the annular space between the out surface of the introducer needle 31 and the inner lumen of the catheter 21. Alternatively, needle hub 34 can include an integrated flashback chamber to take the place of the flashback notch 35. Needle hub 34 is preferably formed from the same types of materials that are used to form catheter hub 24. Preferably, a paddle 36 for holding is extended from the needle hub 34. The catheter 21 is over the introducer needle 31 when assembled.

The safety device includes a needle shield 40 which is preferably make of plastic and a spring clip 50 which is amounted in the needle shield 40, as shown in Fig. 2, 4, and 5. Once the catheter 21 is inserted into a blood vessel and the introducer needle 31 is withdrawal from the catheter, needle shield 40 with the spring clip 50 will hold on the introduce needle tip and protect the user against needle sticks, as shown Fig. 8-10. The needle shield 40 defines a longitudinally extending passage 42. Longitudinally extending passage 42 allows introducer needle 31 to extend longitudinally through needle shield 40. The diameter of extending passage 42 is at least slightly larger than the diameter of the shaft portion of introducer needle 31. This allows the shaft portion of introducer needle 31 to easily pass through the extending passage 42. The extending passage 42 includes a distal portion 44 which encompass the proximal end of the catheter hub 20 before the withdrawal of the introducer needle 31 and a proximal portion 45 which encloses the distal portion of the introducer needle 31 after the withdrawal of the introducer needle 31. The safety device also includes a restriction means 80, which will restrict the needle tip from moving out of the needle shield 40 after the withdrawal of the introducer needle 31.

As shown in Fig. 4 and 5, an opening 60 is provided on the needle shield 40 along the longitudinal axis direction. The opening 60 is communicated with the extending passage 42. The spring clip 50 is fitted in the needle shield 40 through the opening 60. Prior to the

withdrawal of the introducer needle 31, the spring clip 50 will fold into a compressed mode and be abutted by the introducer needle 31 in the compressed mode, and in this case, the spring clip 50 will be at one side of the axis of the introducer needle 31 (see Fig 4, 5 and 7). After the withdrawal of the introducer needle 31, the spring clip 50 will be released by the introducer needle 31 and move back to a uncompressed mode (see Fig 8-10). When the needle tip of introducer needle 31 moves past the spring clip 50 during the withdrawal of the introducer needle 31, it will activate the movement of the spring clip 50 from the compressed mode to the uncompressed mode (it will be referred as "clip activation" in the following context.)

Spring clip 50 of the present invention includes at least one first catch 52, at least one second catch 55, at least one third catch 51 and a tab 53 formed thereon. The first catch 52 and the second catch 55 are adapted to lock the first latch 47 and second latch (not shown) provided on the needle shield 40 for reuse prevention after clip activation. The third catch 51 is adapted to engage a latch 25 formed on catheter hub 24 when spring clip 50 is in the compressed mode prior to clip activation. Tab 53 is provided for preventing the needle movement in the distal direction after clip activation. These will be described in detail in the following.

The spring clip 50 of the first embodiment is shown in Fig. 3, although it could be other shapes, the spring clip 50 could preferably be a V shaped spring clip in the first embodiment. Spring clip 50 is disposed in the needle shield 40 through the opening 60 such that the apex of the V is pointed opposite to the opening 60 and the legs defining the V shape will straddle the longitudinal axis of introducer needle 31 when spring clip 50 is in its uncompressed mode. In this orientation, spring clip 50 is adapted for motion transverse to the longitudinal axis of introducer needle 31 during clip activation. This motion is along a defined path provided by a ramped surface in

needle shield 40. Of course, spring clip 50 could be disposed in needle shield 40 such that the apex is oriented in other positions on a circle concentric to the longitudinal axis of introducer needle 31. All that is required is that spring clip 50 be adapted for motion transverse to the longitudinal axis of introducer needle 31. The apex of the V shape facilitates the flexing of spring clip 50 to and from a compressed condition. In addition, the apex of the V shape could be in the form of a living hinge.

In this embodiment, one of the legs defining the V shape of the spring clip 50 includes a clip arm 54 which extends generally parallel to the longitudinal axis of introducer needle 31. Two fingers are formed on the opposite ends of the clip arm 54. Preferably, the orientation of the two fingers is substantially perpendicular to the longitudinal axis of the introducer needle 31. First catch 52 is formed on one of the fingers, and the third catch 51 is formed on the other of the fingers. In the present embodiment, the first catch 52 could be at least one detent or barb projected from the finger toward the needle shield 40. The first latch 47 could be a detent or a recess formed on the needle shield 40, as better shown in Fig 14.

A finger 56 is formed on the free end of the other leg defining the V shape of spring clip 50 by folding toward the outside of the V shape. The second catch 55 is formed on the finger 56. As shown in Fig 3, the second catch 55 could be at least one detent or barb. When the spring clip 50 is fitted in the needle shield 40, the finger 56 will be inserted to a slot 49 (see Fig 7) formed on the needle shield 40, and the detent or barb will be engaged the second latch such as detent or recess (which is not shown) formed on the inner wall of the slot 49, in such a way, spring clip 50 could not be pulled out of the slot 49 once it is inserted. Alternatively, the second catch 55 could be other designs such as flange formed by folding the free end of the finger

56. All that required is that the second catch 55 and second latch (not shown) should be formed so that the engagement of them would prevent the spring clip 50 from being pulled out from the needle shield 40 after insertion.

Due to the actions of first catch 52 and second catch 55, the user could not reset the spring clip 50 after the clip activation without it being broken, therefore, the reuse of the spring clip or the introducer needle or the assembly is prevented.

As mentioned above, in the first embodiment, the third catch 51 is a finger formed on clip arm 54 which extends generally parallel to the longitudinal axis of introducer needle 31. The third latch 25 could be one of flange, thread, notch, detent or the like formed on the catheter hub 24. Although the use of third catch 51 and the third latch 25 is preferred because it could provide positive mechanical engagement between the needle shield 40 and the catheter hub 24, the third catch 51 and the third latch 25 are not necessary. Without them, the engagement force between the needle shield 40 and catheter hub 24 is limited to frictional force which may be easier to overcome than with mechanical engagement. However, in certain situations, this frictional force may be sufficient.

Tab 53 is provided for preventing the needle movement in the fore direction after clip activation. These will be described in detail in the following. Alternatively, the tab 53 could include a hole (not shown), however, the diameter of the hole should be larger than the main shaft of the introducer needle 31 but smaller than an enlarged discontinuous portion 33 of the introducer needle 31. After the clip activation, the needle tip could insert to the hole, however, the enlarged discontinuous portion 33 will be stopped by said hole.

Fig. 4 shows a state of the catheter and introducer needle assembly

prior to the clip activation of the spring clip 50. In this state, the spring clip 50 folds back into the compressing mode and is disposed in the extending passage 42 of the needle shield 40 through the opening 60. The spring clip 50 is held in the compressed mode by the introducer needle 31. The distal end of the catheter hub 24 is encompassed within the distal portion 44 of the extending passage 42 of the needle shield 40.

Fig 5 shows an alternate view of the state prior to the clip activation of the spring clip 50. The spring clip 50 is held in the compressed mode by the introducer needle 31. The third catch 51 is engaged on a third latch 25 such as a flange provided on the catheter hub 24. Fig 6 more clearly shows the position of the third catch 51 prior to the clip activation. In this state, the third catch 51 projects into the distal portion 44 of the extending passage 42 and engages the third latch 25 on the proximal end of catheter hub 24 so as to actively prevent the needle shield 40 from dislodging from the catheter hub 24.

Fig 7 is an alternate view which shows the state prior to clip activation. The spring clip 50 is held in compressed mode by the introducer needle 31. The third catch 51 is projected into the distal portion 44 which encompass the catheter hub 24.

Fig 8, 9, and 10 shows the state after clip activation of the spring clip 50. Once the catheter 21 is inserted into a blood vessel, the clinician will withdraw the introducer needle 31 from the catheter 21. With the withdrawal movement of the introducer needle 31 from the catheter 21, the spring clip 50 in the compressed mode will be released by the introducer needle 31 after the needle tip of the introducer needle 31 traverses past the spring clip 50, and therefore, the spring clip 50 springs open from the compressed mode to an uncompressed mode. Upon the spring clip 50 springing open, the third catch 51 moves

from the first position of Fig 6 to a second position. As clearly shown in Fig 11, in this second position, the third catch 51 does not project into the distal portion 44 of the extending passage 42, and thus disengage the third latch 25 on catheter hub 24. In this case, the needle shield 40 could freely move in the aft direction and in the same axis as the introducer needle 31. Riding on the same spring-open action, tab 53 of the spring clip 50 will move from a position which is not close a hole 46 on the proximal portion of the extending passage 42 to a position which close the hole 46, and the needle retracts into the proximal portion of the extending passage 42(see Fig 8, 10 and 12). As such, tab 53 prevents the introducer needle 31 from moving in the fore direction and being able to reinsert into the catheter. Meantime, a restriction means 80 is provided to restrict the introducer needle 31 from moving out of the needle shield 40 after clip activation. In this embodiment, the restriction means 80 could be a washer having an opening therein with a diameter slightly larger than the diameter of the main portion of introducer needle 31 but smaller than the diameter of the enlarged discontinuous portion 33. The washer could be placed into a cavity provided in the proximal portion of the needle shield 40 , and the introducer needle 31 passes through the opening of the washer. The washer 80 will stop the enlarged discontinuous portion 33 of the introducer needle 31. As such, the distal portion of the introducer needle 31 will reside, be enclosed and obscured in the proximal portion 45 of the extending passage 42. Thus, any blood remnant on the needle tip is contained in the proximal portion 45 of the extending passage 42.

The washer 80 could be the circular shape (see Fig 2) and could be other shape (see Fig 18). The requirement is that the diameter of the opening of the washer 80 is slightly larger than the diameter of the main portion of introducer needle 31 but smaller than the diameter of the enlarged discontinuous portion 33.

After clip activation, the first catch 52 (obscured from user) on the spring clip 50 will engage the first latch 47 on the needle shield 40 to prevent the spring clip 50 from being recompressed and thus the reuse could be prevented. Through the engagement of the first latch 47 and first catch 52, it will prevent the spring clip 50 from resetting to pre-activation condition, and thus prevent the reuse.

As shown in Fig 10, 12 and 13, the washer 80, which acts as the restriction means, is provided in extending passage 42 of the needle shield 40. The washer 80 has a hole which is small enough to allow the uniform shaft of the introducer needle 31, but blocking an enlarged portion 33 of the introducer needle 31 from passing through. In this way, the washer 80 will prevent the introducer needle from further withdrawal by the hole stopping the enlarged discontinuous portion 33 of the introducer needle 31.

The enlarged discontinuous portion 33, such as a bump, is positioned such that the flashback notch 35(if have) and the needle tip should be enclosed within the proximal portion 45 of the extending passage 42 of the needle shield 40 when the enlarged discontinuous portion 33 is restricted by the washer 80. Also, the bump is situated in front of the notch 35 so that there is no reduction in the flow when the flashback flow occurs. The bump could be a separate ferrule which is amounted on the introducer needle, however, the bump is preferably created by pinching or crimped the introducer needle 31 at the area at two opposing point such that the area is flattened at the crimped area with an obvious bulge being formed in the directions perpendicular to the crimp action. Such a bump could be called "crimped bump".

As shown in Fig. 8, on further withdrawal action of the introducer needle 31, the introducer needle assembly 30 and the needle shield 40 will be released from the catheter hub 24, since the third catch 51 of the spring clip 50 is disengaged from the third latch 25 of the catheter hub 24, and the bump of the introducer needle 31 is stopped by the washer 80 at this time.

Of course, the first catch 52 could be designs other than the first embodiment, for example, Fig 15 -18 show the second embodiment of the safety device of the present invention, wherein first catch 52 of the spring clip 50 could be a detent formed by folding the edge of the finger. All that required is that first catch 52 and first latch 47 should be formed so that the engagement of them after clip activation would prevent the spring clip 50 from being recompressed by the user along the circumferential direction. In addition, the shape of the washer 80 is unnecessary to be a circular shape as shown Fig. 18, all that required is that the diameter of the hole of the washer 80 is larger than the shaft portion of the introducer needle 31 but smaller than the enlarged discontinuous portion 33.

Fig. 19 shows a third embodiment of the safety device of the present invention. In this embodiment, the restriction means 80 is not a washer but a tether 80. The tether could be made of plastic. The tether 80 is folded between the introducer needle hub 34 and the needle shield 40 prior to the withdrawal of the introducer needle 31, and one end of the tether 80 is connected with the introducer hub 34 and the other end is connected with the needle shield 40. After the withdrawal of the introducer needle 31, the length of the tether 80 will restrict the needle tip from moving out of the needle shield 40. Fig. 19 shows the status after the withdrawal of the introducer needle 31. In this embodiment, the discontinuous portion 33 of the introducer needle 31 is unnecessary.

It should be noted, in the first and second embodiment, the washer 80 and the enlarged discontinuous portion 33 of the introducer needle 31 are used; however, the other designs could be used. For example, the restriction means could be another separate spring plate, and the discontinuous portion 33 of the introducer needle 31 is not an enlarged portion but a recess on the introducer needle 31. In this way, the separate spring plate will engage the recess on the introducer needle 31 when the recess of the introducer needle 31 moves past the separate spring plate during the withdrawal of the introducer needle 31. In addition, the restriction means 80 also could simply be a hole in extending passage 42 of the needle shield 40, and the inner diameter of said hole is smaller than the enlarged discontinuous portion 33 of the introducer needle 31 but larger than the shaft portion of the introducer needle.

After the withdrawal of the introducer needle 31, the needle shield 40 will reliably engage and hold on the distal portion of the introducer needle 31 since the restriction means 80 such as washer, tether, or a separate spring plate prevent the distal portion of the introducer needle 31 moving out of the needle shield 40, even though the rotation of introducer needle 31 relative to the needle shield happens during or after the withdrawal of the introducer needle.

The present invention is described with reference to the above embodiments as examples, however, the embodiments should not be understood as restriction to the present invention, it should be noted that the person skilled in the art could make some modifications to the embodiments, and the protect scope of the present invention is only measured by the appended claims.

Claims

1. A safety device for a catheter and introducer needle assembly (10), said catheter and introducer needle assembly (10) comprising: a catheter assembly (20) including: a catheter (21) having a proximal end and a distal end; a catheter hub (24) in fluid communication with the catheter (21) and having a proximal end and a distal end connected to the proximal end of the catheter (21);an introducer needle assembly (30) including: an introducer needle (31) having a proximal end and a distal end and a longitudinally axis, and an needle hub (34) affixed to the proximal end of the introducer needle (31), said introducer needle (31) disposed in the catheter (21); and said safety device, said safety device including:

a needle shield (40) defining a longitudinally extending passage (42) with an opening (60) along the longitudinal direction of the longitudinally extending passage (42), the diameter of which is at least slightly larger than the diameter of the introducer needle (31) so as to allow the introducer needle (31) to pass through the extending passage (42), said needle shield (40) having at least one first latch (47) and at least one second latch formed thereon;

a spring clip (50) having at least one first catch (52), at least one second catch (55) and a tab (53), said spring clip (50) fitted into the needle shield (40) through the opening (60), and the second catch (55) of the spring clip (50) is irreversibly engaged the second latch of the needle shield (40), and said spring clip (50) is adapted to flex between a compressed mode prior to the withdrawal of the introducer needle (31) and an uncompressed mode after the withdrawal of the introducer

needle (31) in a plane substantially perpendicular to the longitudinal axis of the introducer needle; and

a restriction means(80) for restricting the distal end of the introducer needle (31) from moving out of the needle shield (40) after the withdrawal of the introducer needle (31),

wherein, prior to the withdrawal of the introducer needle (31), the spring clip (50) is abutted in the compressed mode by the introducer needle (31) passing through the extending passage (42), and upon the introducer needle (31) moving past the spring clip (50) during the withdrawal of the introducer needle, the spring clip (50) is released by the introducer needle and spring open into the uncompressed mode, and after the withdrawal of the introducer needle (31), the first catch (52) of the spring clip (50) is irreversibly engaged the first latch (47) of the needle shield (40), and the tab (53) moves in front of the distal end of the introducer needle and prevents the distal end of the introducer needle from out of the shield , and the engagement between the first catch (52) and the first latch (47) prevents the spring clip (50) from being recompressed after the withdrawal of the introducer needle (31) and the engagement between the second catch (55) and the second latch prevents the spring clip (50) from being pulled out of the needle shield (40), and the restriction means (80) restricts the distal end of the introducer needle (31) from moving out of the needle shield (40) after the withdrawal of the introducer needle (31).

2. A safety device for a catheter and introducer needle assembly (10) according to claim 1, wherein, the spring clip (50) further including at least one third catch (51) formed thereon, said third catch (51) actively engaging a third latch (25) formed on the catheter hub (24) when the spring clip (50) is in the compressed mode prior to the withdrawal of the introducer needle and disengaging the third latch (25) when the spring clip (50) is in the uncompressed mode after the

withdrawal of the introducer needle.

3. A safety device for a catheter and introducer needle assembly (10) according to claims 1 or 2, wherein, the spring clip (50) is a V shaped spring clip, and the apex of the V is pointed opposite to the opening (60) and legs defining the V shape will straddle the longitudinal axis of introducer needle (31) when spring clip (50) is in its uncompressed mode.

4. A safety device for a catheter and introducer needle assembly (10) according to claims 3, wherein, one of the legs defining the V shape of the spring clip (50) including a clip arm (54) which extends generally parallel to the longitudinal axis of introducer needle (31), and two fingers are formed on the opposite ends of clip arm (54), said first catch (52) is a detent formed on one of said fingers, said first latch (47) is a detent or recess formed on the needle shield (40).

5. A safety device for a catheter and introducer needle assembly (10) according to claim 4, wherein, said first catch (52) is a barb formed on one of said fingers.

6. A safety device for a catheter and introducer needle assembly (10) according to claim 4, wherein, said first catch (52) is a flange formed by folding the edge of said one of said fingers.

7. A safety device for a catheter and introducer needle assembly (10) according to claim 3, wherein the second catch 55 is a detent formed on the other leg defining the V shape of spring clip (50).

8. A safety device for a catheter and introducer needle assembly (10) according to claim 7, wherein the second catch 55 is a detent formed on a finger (56) formed on the free end of the other leg defining the V shape of spring clip (50).

9. A safety device for a catheter and introducer needle assembly (10) according to claim 1, wherein the restriction means (80) is a washer fitted in the needle shield (40) and having a hole, the diameter of which is larger than the diameter of shaft portion of the introducer needle (31) and smaller than an enlarged discontinuous portion (33) of the introducer needle (31), and during the withdrawal of the introducer needle (31), the washer will stop the enlarged discontinuous portion (33).

10. A safety device for a catheter and introducer needle assembly (10) according to claim 9, wherein the tab (53) includes a hole the diameter of which is larger than the shaft portion of the introducer needle (31) but smaller than the enlarged portion (33) of the introducer needle (31).

11. A safety device for a catheter and introducer needle assembly (10) according to claim 1, wherein the restriction means (80) could be a hole on the needle shield (40), the diameter of which is larger than the shaft portion of the introducer needle (31) but smaller than an enlarged discontinuous portion (33) of the introducer needle (31).

12. A safety device for a catheter and introducer needle assembly (10) according to claim 1, wherein the restriction means (80) could be a tether, one end of which is connected to the needle hub (34), and the other end of which is connected to the needle shield (40).

13. A safety device for a catheter and introducer needle assembly (10) according to claim 1, wherein the restriction means (80) could be a separate spring plate which will engage an annular recess discontinuous portion of the introducer needle (31) after the withdrawal of the introducer needle (31).

14. A catheter and introducer needle assembly (10), said catheter and introducer needle assembly (10) comprising:
a catheter assembly (20) including: a catheter (21) having a proximal end and a distal end; a catheter hub (24) in fluid communication with the catheter (21) and having a proximal end and a distal end connected to the proximal end of the catheter (21);

an introducer needle assembly (30) including: an introducer needle (31) having a proximal end and a distal end and a longitudinally axis, and an needle hub (34) affixed to the proximal end of the introducer needle (31), said introducer needle (31) disposed in the catheter (21); and

a safety device, including:

a needle shield (40) defining a longitudinally extending passage (42) with an opening (60) along the longitudinal direction of the longitudinally extending passage (42), the diameter of which is at least slightly larger than the diameter of the shaft portion of the introducer needle (31) so as to allow the introducer needle (31) to pass through the extending passage (42), said needle shield (40) having at least one first latch (47) and at least one second latch formed thereon;

a spring clip (50) having at least one first catch (52), at least one second catch (55) and a tab (53), said spring clip (50) fitted into the needle shield (40) through the opening (60), and the second catch (55) of the spring clip (50) is irreversibly engaged the second latch of the needle shield (40), said spring clip (50) is adapted to flex between a compressed mode prior to the withdrawal of the introducer needle (31) and an uncompressed mode after the withdrawal of the introducer needle (31) in a plane substantially perpendicular to the longitudinal axis of the introducer needle; and

a restriction means (80) for restricting the distal end of the introducer needle (31) from moving out of the needle shield (40) after the withdrawal of the introducer needle (31);

wherein, prior to the withdrawal of the introducer needle (31), the spring clip (50) is abutted in the compressed mode by the introducer needle (31) passing through the extending passage (42), and upon the introducer needle (31) moving past the spring clip (50), the spring clip (50) is released by the introducer needle and spring open into the uncompressed mode, and after the withdrawal of the introducer needle (31), the first catch (52) of the spring clip (50) is irreversibly engaged the first latch (47) of the needle shield (40), and the tab (53) moves in front of the distal end of the introducer needle and prevents the distal end of the introducer needle from moving back, and the engagement between the first catch (52) and the first latch (47) prevents the spring clip (50) from being recompressed by the user after the withdrawal of the introducer needle (31) and the engagement between the second catch (55) and the second latch prevents the spring clip (50) from being pulled out of the needle shield (40) by the user, and the restriction means (80) restricts the distal end of the introducer needle (31) from moving out of the needle shield (40) after the withdrawal of the introducer needle (31).

15.A catheter and introducer needle assembly (10) according to claim 14, wherein, the spring clip (50) further including at least one third catch (51) formed thereon, said third catch (51) actively engaging a third latch (25) formed on the catheter hub (24) when the spring clip (50) is in the compressed mode prior to the withdrawal of the introducer needle and disengaging the third latch (25) when the spring clip (50) is in the uncompressed position after the withdrawal of the introducer needle.

16. A catheter and introducer needle assembly (10) according to

claims 14 or 15, wherein, the spring clip (50) is a V shaped spring clip, and the apex of the V is pointed opposite to the opening (60) and legs defining the V shape will straddle the longitudinal axis of introducer needle (31) when spring clip (50) is in its uncompressed mode.

17. A catheter and introducer needle assembly (10) according to claims 14, wherein, one of the legs defining the V shape of the spring clip (50) including a clip arm (54) which extends generally parallel to the longitudinal axis of introducer needle (31), and two fingers are formed on the opposite ends of clip arm (54), said first catch (52) is a detent formed on one of said fingers, said first latch (47) is a detent or recess formed on the needle shield (40).

18. A catheter and introducer needle assembly (10) according to claim 17, wherein, said first catch (52) is a barb formed on one of said fingers.

19. A catheter and introducer needle assembly (10) according to claim 17, wherein, said first catch (52) is a flange formed by folding the edge of said one of said fingers.

20. A catheter and introducer needle assembly (10) according to claim 14, wherein the second catch (55) is a detent formed on the other leg defining the V shape of spring clip (50).

21. A catheter and introducer needle assembly (10) according to claim 20, wherein the second catch 55 is a detent formed on a finger (56) formed on the free end of the other leg defining the V shape of spring clip (50).

22. A catheter and introducer needle assembly (10) according to claim 14, wherein the restriction means (80) is a washer fitted in the needle shield (40) and having a hole, the diameter of which is larger

than the diameter of shaft portion of the introducer needle (31) and smaller than an enlarged discontinuous portion (33) of the introducer needle (31), and during the withdrawal of the introducer needle (31), the washer will stop the enlarged discontinuous portion (33).

23. A catheter and introducer needle assembly (10) according to claim 22, wherein the tab (53) includes a hole the diameter of which is larger than the shaft portion of the introducer needle (31) but smaller than the enlarged portion (33) of the introducer needle (31).

24. A catheter and introducer needle assembly (10) according to claim 14, wherein the restriction means (80) could be a hole on the extending passage of the needle shield (40), the diameter of which is larger than the shaft portion of the introducer needle (31) but smaller than an enlarged discontinuous portion (33) of the introducer needle (31).

25. A catheter and introducer needle assembly (10) according to claim 14, wherein the restriction means (80) could be a tether, one end of which is connected to the needle hub (34), and the other end of which is connected to the needle shield (40).

26. A catheter and introducer needle assembly (10) according to claim 14, wherein the restriction means (80) could be a separate spring plate which will engage an annular recess discontinuous portion of the introducer needle (31) after the withdrawal of the introducer needle (31).