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 In another technique, the introducer needle is partially withdrawn into the catheter after the initial venipuncture.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 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 enclosing 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 acceptable in an environment that requires accuracy and dependability.

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 needle shield 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 with perfect disengagement accuracy and dependability between the catheter adapter and the needle shield.

The objects of the invention are achieved by a safety device for catheter and introducer needle assembly, said catheter and introducer needle assembly comprising: a catheter assembly including: a catheter that has a proximal end, a distal end, and a catheter hub affixed to the proximal end of catheter; an introducer needle assembly including: an introducer needle having a sharp distal tip, a proximal end, and an enlarged portion between the sharp distal tip and the proximal end, and a needle hub affixed to the proximal end; said safety device slidably connected between the catheter assembly and the introducer needle assembly;

Said safety device including a needle shield which defines a longitudinally extending passage with an elongate opening, a spring clip fitted in the longitudinally extending passage through the elongate opening and a stop means for blocking the enlarged portion of the introducer needle, said longitudinally extending passage allowing the introducer needle to extend longitudinally through needle shield, the spring clip provided with first catch to be engaged with the catheter hub and second catch catching the needle shield, at least part of the spring clip is shaped so as to be compressed by the introducer needle before the introducer needle withdrawal from the catheter assembly and to release and trap the sharp distal tip after

the introducer needle withdrawal from the catheter assembly .

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

a catheter assembly including: a catheter that has a proximal end, a distal end, and a catheter hub affixed to the proximal end of catheter;

an introducer needle assembly including: an introducer needle having a sharp distal tip, a proximal end, and an enlarged portion between the sharp distal tip and the proximal end, and a needle hub affixed to the proximal end; said safety device slidably connected between the catheter assembly and the introducer needle assembly;

an safety device including a needle shield which defines a longitudinally extending passage with an elongate opening , a spring clip fitted in the longitudinally extending passage through the elongate opening and a stop means for blocking the enlarged portion of the introducer needle, said longitudinally extending passage allowing the introducer needle to extend longitudinally through needle shield, the spring clip provided with first catch to be engaged with the catheter hub and second catch catching the needle shield, at least part of the spring clip is shaped so as to be compressed by the introducer needle before the introducer needle withdrawal from the catheter assembly and to release and trap the sharp distal tip after the introducer needle withdrawal from the catheter assembly .

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 catheter and introducer needle assembly with the safety device of the present invention enclosed within.

Fig 2 shows the introduce needle tip enclosed by safety device of the present invention after the withdrawal of the introduce needle.

FIG 3a-d show the safety device comprising the spring clip, fitted into the plastic needle shield from the top and clipped in place by the U feature of the clip and the hole on the clip coinciding with the hole on the needle shield, in which Fig 3a is top view of the safety device, Fig 3b is front view of the safety device, Fig 3c is a perspective view of the safety device, and Fig 3d is a side view of the safety device.

FIG 4a-4g shows the shape of the spring clip of the first embodiment, in which Fig 4a is bottom view of the spring clip, Fig 4b is a front view of the spring clip, Fig 4c is a top view of the spring clip, Fig4e and Fig 4g are two perspective views of the spring clip, and Fig 4f is a side view of the spring clip.

FIG 5a-e show the structure of the needle shield of the present invention, in which Fig 5a is a perspective view of the needle shield, Fig 5b is a side view of the needle shield, Fig 5c is a bottom view of the needle shield, Fig 5d is a front view of the needle shield, and Fig 5e is a top view of the needle shield.

Fig 6 is an enlarged view which shows the needle shield and spring clip enclosing the introduce needle tip at the distal end.

FIG 7 shows the needle shield and spring clip. There are one or more rails positioned on the circumferences of the shield body to allow easy slidability due to minimal contact points.

FIG 8 shows a section view of the safety device of the present invention enclosed by the introducer needle hub and the catheter hub.

FIG 9 shows a magnified section view of part of the introducer needle and catheter assembly, in which the safety device is enclosed by the introducer needle hub and the catheter hub, and the V bend of the spring clip engages the recess on the catheter hub.

FIG 10 shows a stage during the withdrawal of the introducer needle, in which the introducer needle notch is still enclosed by the head of the septum and the distal wall of the spring clip is still compressed by the introducer needle and the V bend engages the recess on the catheter hub.

FIG 11 shows a stage during the withdrawal of the introducer needle, in which the introducer needle tip has moved past the distal wall of the spring clip and the distal wall of the spring clip is released by the introducer needle and trap the introducer needle tip from moving toward the distal direction, and the V bend still engages the recess of catheter hub.

FIG 12 shows a stage during the withdrawal of the introducer needle, in which the V bend disengage the recess of catheter hub and the needle shield is separated from the catheter hub and the bump feature on the introducer needle preventing the introducer needle from moving toward the proximal direction, the extended nose at the proximal end of the needle shield prevent leakage of blood from the introducer needle notch.

FIG 13 shows the introduce needle configuration of the crimped bump followed by the flashback notch.

FIG 14 shows the introduce needle configuration of the 3D bump followed by the notch.

Fig 15a-e shows the safety device of the second embodiment of the present invention, in which Fig 15a is a top view of the safety device, Fig 15b is a front view of the safety device, Fig 15c is a bottom view of the

safety device, Fig 15d is a perspective view of the safety device, and Fig 15e is a side view of the safety device.

Fig 16a-h shows the spring clip used in the safety device of the second embodiment, in which Fig 16a is a left side view of the second spring clip, Fig 16b is a front view of the second spring clip, Fig 16c is a perspective view of the second spring clip, Fig 16d is a right side view of the second spring clip, Fig 16e is a perspective view of the first spring clip, Fig 16f is a left side view of the first spring clip, Fig 16g is a front view of the first spring clip, and Fig 16h is a right side view of the first spring clip.

Preferred Embodiments of the Invention

As used herein, the term "proximal" and "distal" refers to a location on the catheter and introducer needle assembly with respect to the introducer needle hub 34.

As shown in Fig. 1 and 2, the catheter and introducer needle assembly with the safety device of the invention is identified generally by the numeral 10. It includes a catheter assembly 20, an introducer needle assembly 30 and a safety device 40.

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. More preferably, the catheter 21 is formed from transparent material or at least translucent so as to observe the flashback from the flashback notch (if have). 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 an introducer needle 31

having a sharp distal tip 32 defined by bevel and a proximal end connected to needle hub 34. Introducer needle 31 is preferably formed from stainless steel. Preferably, a flashback notch 33 may be provided on the introducer needle 31. Alternatively, the needle assembly can also include a flashback chamber to take the place of the flashback notch. Needle hub 34 could include a radially outwardly extending tab 36 for holding. Needle hub 34 could be formed from the same or different types of materials that are used to form catheter hub 24.

Safety device 40 includes a needle shield 41 which is preferably made of plastic, as shown in Fig. 3a-3d. Once the catheter 21 is inserted into a blood vessel and the introducer needle 31 is removed from the catheter 21, the safety device 40 will hold on the introduce needle tip and protect the user against needle sticks, as shown Fig. 2. Needle shield 41 in turn defines a longitudinally extending passage having a proximal portion 43, a distal portion 44 and a middle chamfer portion 45. Longitudinally extending passage allows introducer needle 31 to extend longitudinally through needle shield 41. The diameter of proximal portion 43, distal portion 44 and the middle chamfer portion 45 is at least slightly larger than the diameter of the main shaft portion of introducer needle 31. This allows the main shaft portion of introducer needle 31 to easily pass through proximal portion 43, distal portion 44 and the middle chamfer portion 45. As shown in Fig. 3a and 3b, an elongate opening 60 is opened on at lease part of the middle chamfer portion 45 along the longitudinal direction.

Safety device 40 also includes a spring clip 50 which preferably made of spring metal. The spring clip 50 is disposed in the middle chamfer portion 45 through the opening 60. The spring clip 50 comprise: a proximal wall 51 defining an opening 52 therein, a middle wall 54, and a distal wall 53, shown in Fig. 4a-4g. As best shown in Fig. 4b (front view of the spring clip 50), the proximal wall

51 is connected to one end of the middle wall 54 with the proximal wall 51 substantially perpendicular to the middle wall 54. The distal wall 53 is connected to the other end of said middle wall 54 with an bend 55 therebetween. Said bend 55 is projected to the side of the middle wall 54 opposite to the proximal wall 51 and the distal wall 53. Preferably, the bend 55 could be an inverted V bend. Said bend 55 of the spring clip 50 will be used as a catch to connect to the catheter hub 24. The distal wall 53 is shaped so that it could be compressed by the introducer needle prior to the clip activation and release after the clip activation. This will be described in detail in the following context.

Preferably, the distal wall 53 has a portion on its free end, the width of which portion is preferably smaller than the other portion of the distal wall. This width reduced portion will be flexed and bent by the introduce needle prior to the clip activation.

Preferably, the proximal wall 51 has a second catch feature 57 on it free end. For example, said second catch feature 57 could be formed by folding the free end of the proximal wall 51 into a U shaped catch. This U shaped catch will snap on a corresponding portion on the inner wall of the needle shield. Said corresponding portion could be an indent provided in the middle chamfer portion 45.

Preferably, the opening 52 has a reinforced lip on the circumference to catch the enlarged portion (such as bump feature) on the introduce needle shaft. Alternatively, the diameter of the enlarged portion of the introducer needle shaft could be smaller than the opening 52, but larger than the proximal portion 43 which could catch the enlarged portion on the introducer needle shaft during the withdrawal of the introducer needle.

As shown in Fig. 3a-3d, the spring clip 50 is fitted in the plastic needle shield 41 through the opening 60 and clipped in place by the

second catch 57 of the clip 50, the opening 52 on the proximal wall 51 coinciding with the proximal portion opening on the needle shield 41. As best shown in fig. 3b, the inverted V shape bend 55 of the spring clip projects beyond the outer wall of the needle shield 41. The distal wall 53 will be interposed the extending passage of the main body 41 between the openings in the proximal portion 43 and the distal portion 44 when the introducer needle finish the withdrawal from the catheter(after clip activation)

Fig. 5a-5e show the structure of the needle shield 41 in the first embodiment of the present invention. The needle shield 41 is moulded from plastic or other material, with a through hole along the axis of the passage of the introducer needle. An indent latch 47 in the plastic is preferably provided in the needle shield 41 for mating to the U shaped catch 57 of the spring clip 50, preventing the spring clip from being dislodged from the needle shield 41.

Fig. 6 shows the needle shield 41 and the spring clip 50 enclosing the introducer needle tip at the distal end after the introducer needle finish the withdrawal from the catheter. The introducer needle is affixed at the proximal end to a needle hub 34 that encloses the safety device 40 from sight when in the configuration shown in Fig.1.

As shown in Fig. 7, there are one or more rails 49 provided on the circumference of the needle shield. Said rails 49 help the needle shield easily slide out of the needle hub 34 due to minimal contact area between the needle shield 41 and the needle hub 34 .

Fig. 8 is a section view which shows the state of the catheter and introducer needle assembly 10 before the introducer needle's withdrawal from the catheter 21, with the safety device 40 enclosed by the needle hub 34 and the catheter hub 24. The proximal end of the safety device 40 is enclosed by the needle hub 34, and the distal

end of the safety device 40 is enclosed by the catheter hub 24. A recess 25 is provided on the catheter hub 24. The inverted V shaped catch of the spring clip 50 is engaged with the recess 25. Fig. 9 shows a magnified section view of the catheter and introducer needle assembly 10 as the state of Fig.8 , in which the introducer needle 31 has been withdrawal slightly .

Although the present invention is described in connection with a catheter assembly 20 with a septum 29, the safety device of the present invention also could be used in connection with the other type of catheter assembly 20, for example, without the septum 29.

During normal use, once the catheter 21 is properly inserted into a blood vessel, the introducer needle 31 which preferably has a flashback notch 33 (see Fig 13 and 14) will be removed from the catheter 21. Fig. 10-12 shows the several phases of the withdrawal of the introduced needle 31 from the catheter assembly 20.

Fig.10 shows a phrase in which the flashback notch 33 of the introducer needle 31 has been moved into and enclosed by the head of the septum 29, at this time, the distal wall 53 of the spring clip 50 is still compressed by the introducer needle.

Fig.11 shows a phrase in which the distal wall 53 of the spring clip 50 springing out as there is no more interference from the introducer needle 31, therefore, the distal wall 53 trap the needle tip from moving back to the distal direction.

Fig.12 a further phrase, in which the introducer needle tip trapped by the distal wall 53 of the spring clip 50 from slidably moving back to the distal direction and the enlarged portion 38 on the introducer needle 31 preventing the introducer needle 31 from slidably moving to the proximal direction. The extended nose 46 at the distal end of the needle shield 41 helps prevent leakage of blood from the needle

tip or the flashback notch 33(if have). On pulling the introducer needle 31 further to the proximal direction, the inverted V shape catch 55 of the spring clip 50 is disengaged from the recess 25 of the catheter hub 24. Thereby, the needle shield 41 is released from the catheter hub 24.

In the above embodiment, the enlarged portion 38 on the introducer needle 31 could be a bump. As shown in Fig 13, the bump could be the crimped bump , preferably, followed by the flashback notch 33. The crimped bump should preferably be manufactured by pinching or crimping the needle at 2 points. The axis of the 2 points must cross and coincide with the axis the introducer needle 31.

As shown in Fig.14, the enlarged portion 38 on the introducer needle 31 also can take many other forms. For example, in the embodiments described herein the enlarged portion 38 is an enlarged diameter portion 38 which can take the form of a bump on a needle such as described in U.S. Pat. No. 5,215,528 the disclosure of which is specifically incorporated herein by reference. Enlarged diameter portion 38 has a medial portion with an outside diameter larger than the outside diameter of the main portion of introducer needle 31, a tapered proximal portion extending from the medial portion toward the proximal portion of introducer needle 31 and a tapered distal portion extending from the medial portion toward the distal portion of introducer needle 31. Although enlarged diameter portion 38 is disclosed as having a symmetrical configuration, this is not required.

Enlarged diameter portion 38 should have a diameter greater than the outer diameter of the shaft portion of introducer needle 31 but should be generally smaller than the inner diameter of the distal portion 44 of longitudinally extending passage. This ensures that introducer needle 31 can be pulled in a proximal direction into safety device 40. In order to prevent introducer needle 31 from being pulled proximally completely out of safety device 40, proximal

portion 43 of longitudinally extending passage should be smaller than enlarged diameter portion 38 to block further movement of introducer needle 31 through proximal portion 43.

Alternatively, and preferably, the diameter of opening 52 of the proximal wall 51 of the spring clip 50 is slightly larger than the diameter of the main portion of introducer needle 31 but smaller than the diameter of enlarged diameter portion 38. In this case, when the introducer needle 31 is moved proximally with respect to safety device 40, the enlarged diameter portion 38 will engages opening 52 of the proximal wall 51, but not proximal portion 43 of the needle shield 41. This prevents introducer needle 31 from being completely removed from needle shield 41 in the proximal direction.

In order to place catheter 21 into a patient's blood vessel, the clinician substantially longitudinally aligns introducer needle 31 and catheter 21 with the target blood vessel. The bevel of the introducer needle tip should be facing substantially away from the skin surface during venipuncture. The clinician inserts introducer needle 31 and catheter 21 at a shallow angle, preferably less than about 35 degrees, into the skin so that sharp distal tip 32 enters the target blood vessel. The clinician then preferably observes a blood flashback in the flashback chamber of needle hub 34 or observes the blood flashback through the flashback notch 33 of the introducer needle 31.

After confirming placement of introducer needle 31 and catheter 21 in the target blood vessel, the clinician advances catheter 21 distally axially along introducer needle 31 into position in the blood vessel. In certain techniques, introducer needle 31 may be partially withdrawn into catheter 21 before catheter 21 is completely advanced into position in the blood vessel. After proper placement of catheter 21 is achieved, the clinician places a finger from her other hand on the patient's skin over the blood vessel approximately over distal end of catheter 21. By placing her finger on the patient's skin

and applying sufficient pressure on the skin, the clinician thereby substantially occludes blood flow through catheter 21 , or if the septum 29 is provided in the catheter assembly 20, the blood flow could be occluded by the septum 29. The clinician then withdraws introducer needle 31 completely from catheter 21 by moving needle hub 34 proximally. This movement causes the tip of introducer needle 31 to move proximally into safety device 40. However, the spring clip's inverted V bend which acts as a catch and the catheter hub's recess cause the needle shield 41 to remain engaged with catheter hub 24 during at least the initial proximal movement of introducer needle 31. Continued proximally directed force applied to needle hub 34 causes inverted V bend to become disengaged from the recess of catheter hub 24 once sharp distal tip 32 is located in safety device 40 and introducer needle 31 is locked therein by spring clip 50. After introducer needle 31 and safety device 40 have been removed from catheter hub 24, the clinician may then attach a fluid delivery device, a PRN or a deadender cap to catheter hub 24 and commence the planned treatment. Introducer needle 31 and needle shield 41 may then be disposed of according to the facility's disposal protocol.

Fig. 15a-e shows the safety device of the second embodiment of the present invention, and Fig. 16a-h shows the spring clip used in the safety device of the second embodiment. Here, only the difference between the first and second embodiment is described. The difference between the first and the second embodiments is that the spring clip 50 of the first embodiment is divided into two parts: the first spring clip 50a and the second spring clip 50b in the second embodiment. The first spring clip 50a includes the middle wall 54 and the distal wall 53, and the bend 55 between them. The second spring clip 50b includes the proximal wall 51 defining the opening 52 therein, and the proximal wall 51 includes the U shaped catch 57 formed by folding its free end. In the second embodiment, the first spring clip 50a is fitted in the needle shield 41 by bonding the free

end of the middle wall 54 onto a corresponding portion of the needle shield 41, and the second spring clip 50b is fitted in the needle shield 41 by engaging the U shaped catch 57 with the indent latch 47 provided in the needle shield 41. Alternatively, the second spring clip 50b of the second embodiment also could be replaced by a washer with a hole, the diameter of which should be larger than the shaft portion of the introducer needle 31, and smaller than the enlarged portion 38 of the introducer needle 31..

It should be noted that the first catch of the spring clip of the present invention could take the other forms for example the spring clip could include a ball hole on the spring clip to take the position of the inverted V shape bend, and said ball hole could be engaged with a ball bearing provided on the catheter hub.

The spring clip 50 of the invention underlying two functions. One function is to protect the user from contacting the introducer needle tip. The other function is to provide a catch such as inverted V shaped bend or the ball hole to engage with the catheter hub 24. If the clip functions were separated, it would need two separate clips and thus double the cost.

Although the present invention is described in conjunction with the above embodiments, it should be noted that the embodiments should not be understood as restriction to the present invention, and the person skilled in the art could make some modifications to the embodiments within the scope of the appended claims, and the scope of the present invention is measured by the appended claims.

Claims

1. Safety device (40) for catheter and introducer needle assembly (10), said catheter and introducer needle assembly (10) comprising: a catheter assembly (20) including: a catheter (21) that has a proximal end, a distal end, and a catheter hub (24) affixed to the proximal end of catheter (21); an introducer needle assembly (30) including: an introducer needle (31) having a sharp distal tip (32), a proximal end, and an enlarged portion (38) between the sharp distal tip and the proximal end, and a needle hub (34) affixed to the proximal end; said safety device (40) slidably connected between the catheter assembly (20) and the introducer needle assembly (30);

Said safety device (40) including a needle shield (41) which defines a longitudinally extending passage with an elongate opening (60), at least one spring clip (50) fitted in the longitudinally extending passage through the elongate opening (60) and a stop means for blocking the enlarged portion (38) of the introducer needle (31), said longitudinally extending passage allowing the introducer needle (31) to extend longitudinally through needle shield (41), said at least one spring clip (50) being provided with first catch (55) to be engaged with the catheter hub (24), at least part of said at least one spring clip (50) is shaped so as to be compressed by the introducer needle before the introducer needle withdrawal from the catheter assembly (20) and to release and trap the sharp distal tip (32) after the introducer needle withdrawal from the catheter assembly (20) .

2. Safety device (40) for catheter and introducer needle assembly (10) according to claim 1, wherein said at least spring clip (50) comprising a proximal wall (51), a middle wall (54), and a distal wall (53), the proximal wall (51)being connected to one end of the middle wall (54), the distal wall (53) being connected to the other end of said middle wall (54), said first catch being a bend provided between the middle wall (54) and the distal wall (53) to be engaged

with the catheter hub (24), said distal wall (53) acting as said at least part of the spring clip (50).

3. Safety device (40) for catheter and introducer needle assembly (10) according to claim 2,wherein the distal wall (53) has a portion on its free end, the width of which portion is smaller than the other portion of the distal wall, and said width reduced portion acting as said at least part of the spring clip (50).

4. Safety device (40) for catheter and introducer needle assembly (10) according to claim 2,wherein, an U shaped feature being formed on the free end of the proximal wall (51), said U shaped feature being used to snap on an indent (47) on the needle shield.

5. Safety device (40) for catheter and introducer needle assembly (10) according to one of claims 2-4, wherein the proximal wall (51) define an opening (52) through which the introducer needle shaft could pass, the inner diameter of the opening (52) is smaller than the enlarged portion (38) of the introducer needle.

6. Safety device (40) for catheter and introducer needle assembly (10) according to one of claims 5, wherein the opening (52) has a reinforced lip on the circumference to catch the enlarged portion (38) on the introducer needle.

7. Safety device (40) for catheter and introducer needle assembly (10) according to one of claims 1-6, wherein the enlarged portion (38) could be one of crimped bump or 3D bump or rolled bump or ferrule on the introducer needle.

8. Safety device (40) for catheter and introducer needle assembly (10) according to claim 2, wherein a recess provided on the catheter hub (24), said bend being engaged with said recess.

9. Safety device (40) for catheter and introducer needle assembly (10) according to one of claims 1, wherein the first catch being a ball hole on top of the spring clip, said ball hole engaged with a ball bearing provided in the catheter hub.

10. Safety device (40) for catheter and introducer needle assembly (10) according to one of claims 1-9, wherein there are one or more rails (49) provided on the circumference of the needle shield.

11. A catheter and introducer needle assembly (10), comprising:

a catheter assembly (20) including: a catheter (21) that has a proximal end, a distal end, and a catheter hub (24) affixed to the proximal end of catheter (21);

an introducer needle assembly (30) including: an introducer needle (31) having a sharp distal tip (32), a proximal end, and an enlarged portion (38) between the sharp distal tip and the proximal end, and a needle hub (34) affixed to the proximal end; said safety device (40) slidably connected between the catheter assembly (20) and the introducer needle assembly (30);

an safety device (40) including a needle shield (41) which defines a longitudinally extending passage with an elongate opening (60) , at least one spring clip (50) fitted in the longitudinally extending passage through the elongate opening (60) and a stop means for blocking the enlarged portion (38) of the introducer needle (31), said longitudinally extending passage allowing the introducer needle (31) to extend longitudinally through needle shield (41), said at least one spring clip (50) being provided with first catch (55) to be engaged with the catheter hub (24), at least part of said at least one spring clip (50) is shaped so as to be compressed by the introducer needle before the introducer needle withdrawal from the catheter assembly

(20) and to release and trap the sharp distal tip (32) after the introducer needle withdrawal from the catheter assembly (20) .

12. A catheter and introducer needle assembly (10) according to claim 11, wherein said at least spring clip (50) comprising a proximal wall (51), a middle wall (54), and a distal wall (53), the proximal wall (51) being connected to one end of the middle wall (54), the distal wall (53) being connected to the other end of said middle wall (54), said first catch being a bend provided between the middle wall (54) and the distal wall (53) to be engaged with the catheter hub (24), said distal wall (53) acting as said at least part of said at least one spring clip (50).

13. A catheter and introducer needle assembly (10) according to claim 12,wherein the distal wall (53) has a portion on its free end, the width of which portion is smaller than the other portion of the distal wall, and said width reduced portion acting as said at least part of said at least one spring clip (50).

14. A catheter and introducer needle assembly (10) according to claim 12, wherein, an U shaped feature being formed on the free end of the proximal wall (51), said U feature being used to snap on an indent (47) on the needle shield.

15. A catheter and introducer needle assembly (10) according to one of claims 12-14, wherein the proximal wall (51) define an opening (52) through which the introducer needle shaft could pass, the inner diameter of the opening (52) is smaller than the enlarged portion (38) of the introducer needle.

16. A catheter and introducer needle assembly (10) according to one of claims 15, wherein the opening (52) has a reinforced lip on the circumference to catch the enlarged portion (38) on the introducer

needle.

17. A catheter and introducer needle assembly (10) according to one of claims 11-16, wherein the enlarged portion (38) could be one of crimped bump or 3D bump or rolled bump or ferrule on the introducer needle.

18. A catheter and introducer needle assembly (10) according to one of claims 12, wherein a recess provided on the catheter hub (24), said V bend being engaged with said recess.

19. A catheter and introducer needle assembly (10) according to one of claims 11, wherein the first catch being a ball hole on top of the spring clip, said ball hole engaged with a ball bearing provided in the catheter hub.

20. A catheter and introducer needle assembly (10) according to one of claims 11-19, wherein there are one or more rails (49) provided on the circumference of the needle shield.