An Introducer Needle for Catheter and Introducer Needle Assembly

Technical Field

The present invention relates to a introducer needle (cannula) with a notch for catheter and introducer needle assembly.

Background of the Prior Art

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.

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 In another technique, the introducer needle is partially withdrawn into the catheter after the initial venipuncture.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 catheter and introducer needle assembly is inserted into the blood vessel, it is important to verify proper placement of the assembly in the blood vessel. Therefore, the clinician confirms that there is flashback of blood in the needle. In order to verify said proper placement of the

assembly, the introducer needle could include a 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. The clinician withdraws the introducer needle, leaving the catheter in place, and attaches a fluid delivery device, a PRN or a deadender cap to the catheter hub. 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 catheter and introducer needle assemblies have been developed. These safety catheter and introducer needle assemblies are provided with spring clip or needle shield which will hold on the introducer needle tip after the withdrawal of the introducer needle and prevent the clinician contacting the needle tip.

The conventional introducer needle with a notch for flashback includes a ferrule, with the ferrule closer to the needle tip than the notch for flashback. When the introducer needle is withdrawn from the catheter, the ferrule will stop the needle tip moving out of the spring clip or needle shield. In such way, the needle tip will be protected into the spring clip or needle shield. US5215528 is one of documents which discloses such kind of safety catheter and introducer needle assemblies.

However, the conventional introducer needle with a notch for flashback and a ferrule is relatively expensive to produce, since it will need a separate step to amount the ferrule on the introducer needle. Apart from the disadvantage of cost, the conventional introducer needle with a notch for flashback and a ferrule may have two other problems. One potential problem is that adhesive may occlude the notch or needle tip opening during the introducer needle bonding process; the adhesive is needed to bond the introducer needle to introducer needle hub. Another potential problem is that the ferrule will inevitably reduce the annular space between the inner lumen of catheter and the introducer needle, which in turn may undesirably cause a slower, or no flashback observed at the notch for flashback.

The present invention just relates to the improvement of the introducer needle with a notch for flashback, which is used for the above catheter and introducer needle assembly, especially I.V. catheter and introducer needle assembly.

Summary of the Invention

The present invention provides an introducer needle for the catheter and introducer needle assembly, comprising a notch and a crimped bump.

Preferably, the notch is closer to the introducer needle tip than the crimped bump.

The crimped bump is formed by compressing the introducer needle in the Y-axis so that the compressed material flows in the X-axis, making a crimped bump in the direction of X- axis, and the inner lumen of the introducer needle being flattened by the compressing.

In one of embodiments, the cross section of the crimped bump is a dumb-bell shape.

The dumb-bell shaped bump is manufactured by pinching or crimping the introducer needle at 2 points, and the axis of the 2 points cross the axis of the introducer needle.

In another embodiment, the cross section of the crimped bump is an elliptical shape.

The elliptical shaped bump is manufactured by crimping the introducer needle by two flat surfaces.

The present invention will be described in the following in conjunction with the best embodiment shown in the following figures.

Brief Description of the Drawings

Fig. 1 schematically shows the configuration of the introducer needle of the present invention, with the crimped bump and notch for blood flashback flow;
Fig. 2a-2d schematically shows how the introducer needle is crimped so as to form the crimped bump;
Fig.3 illustrates the adhesive flow in the introducer needle hub and the introducer needle.

Best Modes of the Embodiments

As used herein, the term "proximal" and "distal" refers to the location on catheter and introducer needle assembly with respect to the clinician who uses the assembly of which the introducer needle tip is farthest away from the clinician.

Fig. 1 schematically shows part of the catheter and introducer needle assembly with the introducer needle in accordance with the present invention. The catheter and introducer needle assembly in Fig. 1 has been inserted into the blood vessel. As shown in Fig. 1, the catheter 2 is over the introducer needle 1. The tubing of the catheter is of transparent or at least translucent material. The introducer needle 1 include a notch for flashback 3 and a crimped bump 4.In the embodiments, the notch for flashback 3 is closer to the needle tip than the crimped bump. After the catheter and introducer needle assembly is inserted in the blood vessel, the clinician has to verify proper placement of the assembly in the blood vessel, i.e. the clinician confirms that there is flash back of blood in the introducer needle. The arrow line signed 5 shows the flash back flow of the blood in the introducer needle. The blood flashback can be observed in the annular space between the introducer needle and the catheter since the catheter tubing 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. The clinician withdraws the introducer needle, leaving the catheter in place. The occlusion can also be achieved by other means, for example, the use of septum.

Fig. 2a-2d shows best embodiments of how the crimped bump 4 of the introducer needle is manufactured. Fig. 2a is a top view of the introducer needle 1, with the notch 3 opening on the top. Fig. 2b is a side view of the introducer needle 1. Fig. 2c is a section view of the crimped bump of one embodiment along the line A-A of Fig. 2b. Fig. 2d is a section view of the crimped bump of another embodiment along the line A-A of Fig. 2b.

In order to help the description, it is necessary to establish a coordinate system. With respect to Fig. 2a, the X axis is along the direction from the bottom of the paper to the top, and the Y axis is perpendicular to the paper.

As shown in Fig. 2c-2d, the introducer needle 1 of the present invention is compressed in the Y-axis, and the compressed material flows in the X-axis, making a crimped bump in the direction of X- axis. The inner lumen 9 of the introducer needle 1 is flattened by compressing action.

As shown in Fig. 2d, the crimped bump 4 is manufactured by pinching or crimping the introducer needle at 2 points. The axis of the 2 points must cross the axis of the introducer needle 1. Due to the pinching or crimping, the cylindrical body of the introducer needle obtains a dimensionality change, that is to say, the cylindrical body of the introducer needle is compressed via crimping into a dumb-bell shaped bump, resulting in a symmetry change. In doing so, the inner lumen 9 of the needle is flattened while the compressed material flows to the two sides and forms a dumb-bell shape by conservation of mass.

As shown in Fig.2c, in another embodiment of the present invention, the cross section of the crimped bump also could be crimped into ellipse shape by two flat surfaces.

Preferably, the notch for flashback 3 is closer the needle tip than the crimped bump 4. In this way, the crimped bump 4 will have two functions. One function acts as a stop to prevent introducer needle tip from moving out of the spring clip or needle shield (not shown in the Figures), the other function is to prevent the adhesive from flowing into the lumen of introducer needle by the flattened inner lumen of the crimped bump 4, and this function will be described in more detail with reference to Fig. 3.

It should be noted, the annular space difference between the inner lumen of the catheter tubing and outer surface of the introducer

needle should be sufficient/adequate for fast flashback flow without compromising the flow by the crimped bump 4.

The introducer needle 1 of the invention with a notch for flashback 3 and crimped bump 4 has several advantages over the conventional introducer needle.

The conventional introducer needle with a notch for flashback includes a stop ferrule which has to be closer to the needle tip than the notch. Or if the notch is closer to the needle tip than the ferrule, the ferrule, which has a circular cross section, would block the flashback path of the blood between the introducer needle and the inner lumen of the catheter, and the flashback will not occur.

In addition, during the assembly of the introducer needle 1 and the introducer needle hub 6, it is needed to dispense the adhesive at the postion signed by the arrow 7 to bond them, as shown in Fig.3. Therefore, in order to prevent the adhesive from flowing into the lumen of the introducer needle along the direction signed by the arrow 8 and block the notch, the manufacturing process of the prior art must include a step of crimping the proximal end of the introducer needle, and in this way, it will prevent the adhesive flowing into the lumen of the introducer needle.

However, in the introducer needle 1 of the embodiments of the invention, the position of the notch 3 is preferably closer to the needle tip than the crimped bump 4. Since the crimped bump 4 has a flattened cross section, it would not block the flash back path of the blood between the introducer needle and the inner lumen of the catheter. As shown in Fig. 1, this configuration of the introducer needle 1 is optimized for the flashback blood to smoothly flow out from the notch for flashback 3 to the proximal end, flowing past the crimped bump.

The last but not the least, as shown in Fig. 3, during the assembly of the introducer needle 1 and the needle hub 6, it is need to dispense

adhesive to bond the introducer needle 1 and the needle hub 6. Therefore, it will have a potential flow of the adhesive into the inner lumen of the introducer needle which will undesirably block the notch 3 and in turn the flash back flow. As mentioned above, additional process step is needed to solve the problem of adhesive flowing into the inner lumen of the introducer needle 1 for the prior art. However, in the present invention, no additional process step is needed to prevent adhesive from flowing into the inner lumen of the introducer needle, since the flattened inner lumen of the crimped bump 4 will restrict the adhesive to flow to block the notch 3. Therefore, the crimped bump 4 of the present invention will have two functions. One serves as a ferrule stop which prevent the introducer needle 1 move out of the spring clip or needle shield, the other serves as a restricting flow barrier for the adhesive, which is the function of the crimped proximal end of the introducer needle of the prior art. Therefore, the crimped bump 4 of the present invention will be inexpensive option compared to a ferrule design of the prior art.

It should be noted, although the position of the notch 3 and the crimped bump 4 could be reversed, i.e. the crimped bump 4 is closer to the needle tip than notch 3, the flashback blood would be restricted to some extent by the flattened and reduced space in the inner lumen of the introducer needle 1 at the crimped bump before exiting through the notch 3 to the proximal end. In such a case, during the assembly of the introducer needle 1 and the needle hub 6, it is need to crimp the proximal end of the needle to prevent the adhesive from flowing into the lumen of the introducer needle and blocking the notch for flashback 3.

The present invention is described with reference to the above embodiments as examples, however, the embodiment 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. An introducer needle for a catheter and introducer needle assembly, comprising a notch, a crimped bump, and a sharpened distal tip, wherein the crimped bump is formed by compressing the introducer needle at two points in the Y-axis so that the compressed material flows in the X-axis forming a top and bottom flattened surface, making a crimped bump in the direction of the X-axis, and the inner lumen of the introducer needle being flattened by the compressing, wherein the notch and crimped bump are positioned on the introducer needle such that the notch, the top flattened surface, and the sharpened distal tip all face upward when the bottom flattened surface faces downward.

2. The introducer needle for the catheter and introducer needle assembly in accordance with claim 1, wherein the notch is closer to the introducer needle tip than the crimped bump, and an uncrimped portion of the needle exists between the notch and the crimped bump.

3. The introducer needle for the catheter and introducer needle assembly in accordance with claim 1, wherein the cross section of the crimped bump is a dumb-bell shape.

4. The introducer needle for the catheter and introducer needle assembly in accordance with claim 3, wherein the dumb-bell shaped bump is manufactured by pinching or crimping the introducer needle at 2 points, and the axis of the 2 points cross the axis of the introducer needle.

5. The introducer needle for the catheter and introducer needle assembly in accordance with claim 1 or claim 2, wherein the cross section of the crimped bump is an elliptical shape.

6. A method for forming, on a notched introducer needle having a sharpened distal tip for a catheter and introducer needle assembly, a feature for preventing withdrawal of the introducer needle from a needle

shield or spring clip, the method comprising:

forming an elliptical crimped bump on the needle by compressing the introducer needle in the Y-axis so that the compressed material flows in the X-axis, making a crimped bump in the direction of the X-axis, wherein the inner lumen of the introducer needle is flattened by the compressing, and wherein the bump is configured to have an elliptical shape by crimping the introducer needle between two flat surfaces thereby forming a top flattened surface and a bottom flattened surface on the introducer needle, wherein the notch and crimped bump are positioned on the introducer needle such that the notch, the top flattened surface, and the sharpened distal tip all face upward when the bottom flattened surface faces downward.

7. An introducer needle, substantially as herein described with reference to the accompanying drawings.

8. A method, substantially as herein described with reference to the accompanying drawings.