

SMART FISTULA NEEDLE FOR SAFE FISTULA CANNULATION AND OTHER VASCULAR PROCEDURES

Field of the Invention

5 This invention relates to a smart vessel wall penetration detection needle device for fistula cannulation and other various vascular procedures. This invention further relates to a method of operating the smart vessel wall penetration detection needle device.

Prior Art

10 Many vascular procedures such as central venous catheter insertion, dialysis catheter insertion, arterial angiograms, etc. are conducted on a daily basis across the globe. Such vascular procedures require a skilled medical person to complete the task. Even so, there would be times where a skilled medical person may accidentally insert the needle too deep and puncturing through the vessel. Therefore, those skilled in the art are striving to
15 provide an improved device for penetrating vessel wall.

Summary of the Invention

 The above and other problems are solved and an advance in the art is made by a device in accordance with this invention. A first advantage of the device in accordance with
20 this invention is that the device can replace the use of the traditional dialysis venula to perform cannulation of the fistula and maintain haemostasis during dialysis with greater ease of use and enhanced safety. The sensing means would substantially improve the ease to locate and pierce the lumen, making it less skill intensive. The smart sensing stylet working in tandem with the flexible tubing concept can significantly improve the safety of
25 the device by eliminating accidental puncture of vessels and back-walling.

 A first aspect of the disclosure describes a device for penetrating vessel wall. The device comprises a trigger housing having a resilient means, a trigger haemostatic valve

and a trigger arranged between the resilient means and the trigger haemostatic valve, the resilient means arranged to urge the trigger towards the trigger haemostatic valve; a catheter housing having a flexible catheter tube, a needle provided within the flexible catheter tube with a sharp end extending from one end of the flexible catheter tube, a stylet provided within the needle with one end coupled to the trigger and an opposing end extending out of the sharp end of the needle; and a flash back chamber arranged between the catheter housing and the trigger haemostatic valve, wherein the trigger is between an extended position where the stylet extends out of the needle shielding the needle and a retracted position where the trigger moves away from the trigger haemostatic valve retracting the stylet and exposing the needle.

In accordance with an embodiment of the first aspect, the catheter housing further comprises a catheter haemostatic valve provided at an end opposing the sharp end of the needle and arranged such the flash back chamber is between the catheter haemostatic valve and the trigger haemostatic valve.

In accordance with an embodiment of the first aspect, the flash back chamber is translucent.

In accordance with an embodiment of the first aspect, the resilient means is a spring.

A second aspect of the disclosure describes a method for penetrating vessel wall using the device according to first aspect of the disclosure. The method comprising: moving the trigger to the retracted position and position the device such that the needle is aligned to a target piercing entry point; piercing a skin; observing the flash back chamber and continue to insert the needle; releasing the trigger in response to observing fluid in the flash back chamber; advancing the flexible catheter tube; and removing the catheter housing together with the stylet and needle, the flash back chamber and the trigger housing, leaving behind the flexible catheter tube and catheter haemostatic valve.

Brief Description of the Drawings

The above and other features and advantages in accordance with this invention are described in the following detailed description and are shown in the following drawings:

Figure 1 illustrating a perspective view of a smart vessel wall penetration detection device in accordance with an embodiment of this invention;

Figure 2 illustrating an exploded view of the smart vessel wall penetration detection device in accordance with an embodiment of this invention;

Figure 3 illustrating a cross sectional view of the smart vessel wall penetration detection device in accordance with an embodiment of this invention;

Figure 4 illustrating a side view of the smart vessel wall penetration detection device with the trigger in the extended position in accordance with an embodiment of this disclosure;

Figure 5 illustrating a side view of the smart vessel wall penetration detection device with the trigger in the retracted position in accordance with an embodiment of this disclosure;

Figure 6 illustrating a process flow of using the smart vessel wall penetration detection device in accordance with an embodiment of this disclosure;

Figure 7 illustrating a position of the smart vessel wall penetration detection device with the needle aligned to the target piercing entry point in accordance with an embodiment of this disclosure;

Figure 8 illustrating piercing the skin of the patient in accordance with an embodiment of this disclosure; and

Figure 9 illustrating inserting the needle and cutting through the tissue wall and the fistula wall in accordance with an embodiment of this disclosure.

Detailed Description

This invention relates to a smart vessel wall penetration detection needle device for fistula cannulation and other various vascular procedures. This invention further relates to a method of operating the smart vessel wall penetration detection needle device.

5 It is envisioned that a smart vessel wall penetration detection device in accordance with embodiments of this invention enables a user to gauge the intravascular position of distal end of the needle and automatically deploys a smart sensing stylet after needle puncture of fistula to prevent accidental back-walling during further needle travel.

Figure 1 shows a perspective view of a smart vessel wall penetration detection
10 device 100 in accordance with an embodiment of this invention. Figure 2 shows an exploded view of the smart vessel wall penetration detection device 100 in accordance with an embodiment of this invention. Figure 3 shows a cross sectional view of the smart vessel wall penetration detection device 100 in accordance with an embodiment of this invention.

The smart vessel wall penetration detection device 100 comprises a catheter
15 housing 110, a trigger housing 120, a flash back chamber 130 and a handle 140 coupled to one end of the trigger housing 120.

The catheter housing 110 comprises a flexible catheter tube 111, a needle 113 provided within the flexible catheter tube 111 with a sharp end extending from one end of the flexible catheter tube 111, a smart sensing stylet 114 provided within the needle and a
20 catheter haemostatic valve 112 provided at an end opposing the sharp end of the needle 113.

The trigger housing 120 comprises a trigger 121, a resilient means 122 and a trigger haemostatic valve 123. The trigger 121, resilient means 122 and trigger haemostatic valve 123 are housed within the trigger housing 120 and arranged such that the trigger is between
25 the resilient means 122 and trigger haemostatic valve 123. The resilient means 122 may be a spring or other similar parts that urges the trigger 121 towards the trigger haemostatic valve 123.

The smart sensing stylet 114 is spring actuated to prevent accidental back walling of the fistula wall during cannulation. Specifically, the smart sensing stylet 114 is provided within the needle 113 and extends to the trigger housing 120 and coupled to the trigger 121. A portion of the trigger 121 extends out of the trigger housing 120 to allow a user to
5 move the trigger 121 between an extended position where the stylet extends out of the needle shielding the needle and a retracted position where the trigger moves away from the trigger haemostatic valve, as shown by arrow 121a, retracting the stylet and exposing the needle. To operate the smart vessel wall penetration detection device 100, a user will move the trigger 121 from the extended position as shown in figure 4 to a retracted position
10 as shown in figure 5 and back to the extended position by releasing the trigger.

The flash back chamber 130 is arranged between the catheter housing 110 and the trigger housing 120. More specifically, the flash back chamber 130 is arranged between the catheter haemostatic valve 112 and the trigger haemostatic valve 123. Since the smart sensing stylet 114 and the needle 113 extends through the catheter haemostatic valve 112,
15 blood is allowed to flow through the catheter haemostatic valve 112 and into the flash back chamber 130. The trigger haemostatic valve 123 will prevent blood from flowing out of the flash back chamber, trapping the blood within the flash back chamber 130.

The flashback chamber 130 is provided to gauge the intravascular position of the needle during puncture. The flashback chamber 130 is translucent to allow user to observe
20 blood flowing into the flash back chamber 130. A trigger 121 engages the stylet 114 and moves the stylet 114 to retract the stylet 114 exposing the needle 113 and release the stylet 114 shielding the needle 113 during the cannulation process. Two haemostasis valves are incorporated into the device 100 where a trigger haemostatic valve 123 located at the trigger housing 120 is provided to prevent blood leakage into trigger 121 and a catheter
25 haemostatic valve 112 in the catheter housing 110 is provided to reduce and prevent blood leakage during needle removal. Both needle 113 and stylet 114 will be removed from the device while retaining the flexible catheter tube 111 inside the fistula to draw or deliver fluid.

In summary, the smart vessel wall penetration detection device 100 has the following features:

1. Smart sensing stylet is in extended position prior to use to protect user from accidental needle poke compared to conventional fistula needles.
- 5 2. Flash back chamber is provided as a sensing means to gauge the intravascular position of the distal end of the needle.
3. Spring actuated trigger that conceals smart stylet to enable puncture of fistula wall followed by automatic propulsion of said stylet upon release of trigger.
4. Needle and stylet removable to provide a safer and more comfortable
10 drawing or delivering of fluid to a subject.

We now turn to describe the mode of operating the smart vessel wall penetration detection device 100. Figure 6 illustrates a process 600 of using the smart vessel wall penetration detection device 100. When not in use, the smart sensing stylet 114 is in the forward (extended) position which shields the sharp needle stylet as shown in figure 4. Prior
15 to inserting the flexible catheter tube into a patient's fistula, the sharp needle must be used to puncture the skin, tissue and fistula wall. Before performing the cannulation, a user will stretch the skin of the patient with one hand. Thereafter, process 600 begins with step 610 where the user moves the trigger 121 to the retracted position and position the smart vessel wall penetration detection device 100 at a certain angle as shown in figure 7 with the needle
20 113 aligned to the target piercing entry point. In this position, a spring actuated trigger mechanism engages the said stylet to retract it to expose the needle for cannulation as shown in figure 5. The spring actuated trigger 121 will engage the stylet 114 to retract backwards and expose the sharp end of the needle 113. The user will then proceed to pierce the skin of the patient in step 620 as shown in figure 8.

25 In step 630, the user will then observe the flash back chamber 130 and continue to insert the needle 113 cutting through the tissue wall 710 till it cuts through the fistula wall 720 as shown in figure 9. Once the fistula wall 720 has been penetrated, blood 730 will

travel up the needle 113 and enter the flash back chamber 130. The flash back chamber 130 will indicate the placement of the needle and allows the nurse to gauge the depth of the needle inside the patient. Once flash back is observed, the user releases the trigger 121 as shown in figure 9. The release of the trigger 121 will cause the stylet 114 to propel forward and return to its extended position, shielding the needle 113 from further puncture or back walling into the opposite wall of the fistula.

In step 640, the user advances the flexible catheter tube 111 forward while holding on to the trigger housing 120. The user will continue to advance flexible catheter tube 111 till it is almost completely inside fistula and thereafter remove the catheter housing 110 together with the smart stylet 114, needle 113, flash back chamber 130 and trigger housing 120, leaving behind the flexible catheter tube 111 and catheter haemostatic valve 112.

Process 600 ends after step 640.

The smart stylet 114 is fastened with adhesive and removed without the use of nut and threaded connection. After puncture of the fistula wall 720, the catheter housing 110 together with the smart stylet 114 and needle 113 are removed from the flexible catheter tube 111 and catheter haemostatic valve 112 to allow blood to travel through the flexible catheter tube 111 up until the catheter haemostatic valve 112.

In short, smart vessel wall penetration detection device 100 requires trigger 121 to be retracted longitudinally to retract the stylet 114 and expose needle 113 to perform puncture followed by release of trigger 114 to propel the stylet 114 forward ahead of needle 113 to shield the needle 113.

The above is a description of exemplary embodiments of a device in accordance with this disclosure. It is foreseeable that those skilled in the art can and will design alternative devices based on this disclosure.

Claims

1. A device for penetrating vessel wall comprising:

5 a trigger housing having a resilient means, a trigger haemostatic valve and a trigger arranged between the resilient means and the trigger haemostatic valve, the resilient means arranged to urge the trigger towards the trigger haemostatic valve;

a catheter housing having a flexible catheter tube, a needle provided within the flexible catheter tube with a sharp end extending from one end of the flexible catheter tube,

10 a stylet provided within the needle with one end coupled to the trigger and an opposing end extending out of the sharp end of the needle; and

a flash back chamber arranged between the catheter housing and the trigger haemostatic valve, wherein the trigger is between an extended position where the stylet extends out of the needle shielding the needle and a retracted position where the trigger
15 moves away from the trigger haemostatic valve retracting the stylet and exposing the needle.

2. The device according to claim 1 wherein the catheter housing further comprises:

a catheter haemostatic valve provided at an end opposing the sharp end of the
20 needle and arranged such the flash back chamber is between the catheter haemostatic valve and the trigger haemostatic valve.

3. The device according to claim 1 wherein the flash back chamber is translucent.

25 4. The device according to claim 1 wherein the resilient means is a spring.

5. A method for penetrating vessel wall using the device according to claim 1, the method comprising:

moving the trigger to the retracted position and position the device such that the needle is aligned to a target piercing entry point;

piercing a skin;

observing the flash back chamber and continue to insert the needle;

5 releasing the trigger in response to observing fluid in the flash back chamber;

advancing the flexible catheter tube; and

removing the catheter housing together with the stylet and needle, the flash back chamber and the trigger housing, leaving behind the flexible catheter tube and catheter haemostatic valve.

10