Provisional Patent Application Improved hypodermic Needle Having a Cannula to Cut and Trocar that Permits Fluid Passage By Dr. Stephen Roman

Field of Invention

My invention is in the field of Hypodermic needles. The needles having a cutting cannula, and or having a trocar that retracts sufficiently to allow fluid passage through a passage or passages built into the cannula.

Prior Art

In 1981 Khosrow Jamshidi filed for and later received patent US4266555A. This invention is related to the gripping of the needle and the grip aiding the cutting of the bone allowing the needle to be inserted. Herein is his abstract.

"An elongated hollow biopsy needle assembly which includes a cannula, a stylet arranged to be received within the cannula, a finger-gripping means, and coupling means for orienting the stylet within the cannula and for releasably securing both the cannula and the stylet to the finger-gripping means. The cannula is provided with a generally cylindrical hub which has a bore extending axially thereof, and generally in continuation with the bore of the cannula, with a conical syringe receiving counterbore being formed within the proximal end of the hub. The stylet is provided with a cap member, with the distal-facing surface of the cap being arranged to fit snugly against the proximal-facing surface of the cylindrical hub, to achieve substantially closed symmetrical mating end surfaces between the cannula and stylet, and a substantially air-tight cannula. The distal end of the cannula terminates along a plane disposed at a certain acute angle relative to the axis of the cannula, and the distal end of the stylet terminates along a plane disposed at the same angle relative to its axis. In order to achieve orientation of the stylet relative to the cannula, a groove is formed along the proximal end of the stylet, and the cap is provided with an inwardly extending

tongue arranged to mate with the stylet groove, thereby achieving positive orientation of the stylet relative to the cannula."

This invention is important in that there was recognition that the cutting of the bone required special devices and this device was the art until recently. My invention is a more efficient way for the cutting of the bone to occur allowing a cleaner, less painful procedure.

In 2008, Tyler Allee applied for and later received patent US8343133B2. In his application, Tyler discloses a outer cannula needle having a tip and a threaded collar. The rotation of the needle will control the depth the needle can be inserted into the marrow.

I do not utilize a rotary needle in my invention.

In 1992 patent US5331972A was applied for by Suresh Wadhwani and Greg Smith. The invention was for a stylet and cannula having teeth used to cut the bone. The part of the independent claim of significance to us is the following;

"a removable stylet having first and second ends, said stylet extending through said cannula from said handle, and said second end of said stylet extending beyond said second end of said cannula, said second end of said stylet having a tip having first and second tip surfaces which form an obtuse angle, and first and second cutting surfaces which connect said tip surfaces, said cutting surfaces forming an acute angle."

In my invention, I may utilize a combination stylet and cannula to cut into the bone, but whereas Wadhwani and Smith combination of stylet and cannula form an acute angle, my cutting edge will create an obtuse angle.

Larry Matthews in patent 4306570 invented dual tube rotation in opposite directions where the ends of the cutting device are used to cut into bone for the purpose of extracting a sample of marrow or cartilage.

I may utilize a dual action cutting combination of the stylet and cannula, but they will not rotate in opposite directions.

Patent US4838282A was issued in 1989 to Robert Strasser. The Strasser invention was for the ability to interlock the cannula and the stylet during the cutting process to ensure stability during the cutting process, where the cannula and the stylet both have cutting edges.

While I may also utilize the interlocking of the stylet and the cannula during the cutting portion of the procedure, I do not claim any of this as my art.

In 2008 PCT application US20080243163A1, was applied for and denied. The independent claim of this application reads as follows.

1. Perforating trocar (1), in particular for bone biopsy, of the type comprising a rigid tube (2) in which a rod (3) with a perforating distal tip is able to slide, wherein the zone of the distal tip of the rod has the form of a perforating drill-bit that is able to turn on its axis, while the distal end of the tube is divided into at least two segments (10, 11) with a helical cutting edge.

The unique aspect of this invention is the combination of a trocar with a distal tip and a helical cutting edge on the cannula. My invention in some instances involve a trocar having a cutting edge that works with a cutting edge on the cannula, but that edge is not helical.

In 2007, Larry miller and a group of other inventors claimed a Bone Marrow Aspiration Device. The abstract of the EU patent reads as follows.

"Various devices and methods may be provided to aspirate bone marrow from an associated bone using a powered drive and an aspiration needle or aspiration needle set. Such aspiration devices and methods may also be used in association with stem cell transplant procedures. The aspiration devices may include a coupler assembly, a containment bag or sterile sleeve, an ejector and/or an ejector funnel. An aspiration needle set may include a cannula and trocar with respective tips having optimum configurations, dimensions and/or orientations relative to each other to optimize penetration of a bone and/or bone marrow with minimum trauma to a patient. Exterior portions of some cannulas may include markings to indicate depth of penetration into associated bone marrow. Some cannulas may include one or more side ports for use during aspiration of bone marrow." My invention may utilize such a rotational device to ease the cutting process of the bone by my invention, but I am not adding any new art to the rotational device itself.

The first notation of the use of a trocar in a hypodermic needle was in a French patent #716726A by an Arnault Tzanck going back to 1931. In Tzanck patented the use of the trocar in a hollowed-out needle. The need was for a clean puncture at times and having a trocar allowed the needle to pierce the skin cleanly and not introduce any foreign substance on the skin into the body when puncturing the skin.

Richard Spademan received patent # US3313299A in 1964. Spademan introduced the idea of using a soft flexible catheter when patients needed to maintain a catheter in their vein for a prolonged period of time. By making the catheter flexible, there became a need for a means to make a puncture in the skin to introduce the catheter but then withdraw the hard-puncturing means for comfort of the patient. Spademan introduced the idea of the trocar being used to create the puncture, and then the trocar is withdrawn from the catheter.

In 1967 Sidney Hrisch received a patent # US3352306A for the use of a trocar in conjunction with a cannula. A cannula has a blunt tip not to be used for injecting, so the use of a trocar that is removable allows the cannula to be introduced into the vein via a puncture made by a trocar.

In 1974 a Stephen Jacobson and his staff filed for and soon thereafter received patent # US4180068A. This patent introduced the concept of the trocar having cutouts within, so that upon puncturing of a vein, the trocar may be extended to allow the fluids to flow from the intake side port to the interior of the vein. Jacobson allows for up to two ports within the needle with passageways around the trocar when extended into the vein. When the trocar is not extended, the trocar tip which is larger than the remainder of the trocar body, blocks the flow of the fluids from both of these side ports.

My Invention

What I claim as new art is a bone aspiration needle made up of a trocar having a cutting edge, that extends from a cannula. The trocar is able to slide within the cannula and is activated by a motion of a slide activation. The end of the cannula that has the cutting edge beveled. The beveled edge may be the same angle as the cutting edge of the trocar, or the trocar exterior surface and the exterior surface of the cannula form an obtuse angle. The trocar may lock within the cannula during the bone cutting process.

The cannula beveled edge may have on the beveled surface cutting edges raised from the bevel surface. These edges may be angled different that the principal edge, so that the cutting surface may be at different heights. The difference in the raised edge height may be the lowest off the floor of the cannula surface, near the trocar, and this edge may increase in height as it moves away from the trocar.

The cutting beveled edge of the trocar advantage over the current technology is first that the bone fragments, skin, or soft tissue does not get pushed into the marrow causing possible infection and comfort issues. Secondly, the cannula is able to gain access to the bone marrow without having to be forcibly pushed into the bone. This pressure is uncomfortable, and it may cause a fracture of the bone itself.

A variation to the above-mentioned device is if the cannula has one or more side ports, where these side port or ports, may be used for introducing fluids into a patient, or withdrawing fluids from a patient. There is a trocar in the hypodermic needle used for making an insertion free of unwanted matter that may accompany a normal hypodermic needle insertion. This trocar may be withdrawn past the side ports of the needle to allow the fluids feeding through the side ports to access the interior of the patient or for withdrawal from the patient, free of the contaminants that may arise in the normal insertion of a hypodermic needle without a trocar.

The trocar is still engaged within the said hypodermic needle, but part of the trocar is withdrawn from the needle to allow the side port or ports, to flow the fluids into the patient.

Another use of this trocar being partially withdrawable from the hypodermic needle may be in the removal of fluids from the body of the user, perhaps in an organ that needs fluid removal. In such a case having a trocar introduce a clean puncture is desirable in keeping the unwanted matter from entering the organ during the puncturing process. The trocar partial removal past the side port which is now used for removal of the fluids within the organ, yet the trocar is available to be extended to block further removal of the fluids and allow a clean removal of the hypodermic needle with the trocar.

A feature of my invention, is the trocar may be secured into the extended position by a mechanical means, thereby allowing the medical personal administering the insertion to do so free of the fear of trocar retraction during the insertion procedure.

The cutting cannula having side ports is one variation of the device, but the device can be used solely as the cutting cannula version without the side ports and the trocar that can be retracted past the side port or ports locations. In addition, the device can also be made without the cutting cannula and utilize only the trocar that retracts past the locations of side ports.

My invention is an improvement in the art, it is novel and therefore it is worthy of patent protection.

<u>Claims</u>

What I claim is as follows:

1. A bone marrow aspiration needle having an insertable trocar that has a cutting edge at the end of the trocar, where the needle is a hollow cannula which

the trocar may slide into, with the cannula having a beveled edge, and on that beveled edge existing raised edges that are for cutting bone, and where the cutting edge of the trocar and the beveled edge of the cannula have a corresponding angle, or form an obtuse angle in relation to the exterior surfaces of the trocar and the cannula.

2. The bone aspiration needle in claim 1, where the trocar is moveable by a control on the exterior of the device.

3. The Trocar described in claim 1, where the trocar can be locked into position, or multiple positions within the cannula.

4. The cannula described in claim 1, where the cannula beveled edge of the cannula has sharp protrusions on the surface of the beveled edge, and those protrusions are lower in height near the top of the cannula, near the exit point of the trocar out of the tip of the cannula, and where those edges are increasing in height as the edge moves down the cannula away from the trocar exit point.

5. The beveled edge of the cannula, as per claim 1, where the cannula bevel angle is similar to the cutting surface angle of the trocar.

6. The beveled edge of the cannula, as per claim 1, where the cannula bevel angle creates an obtuse angle with the trocar cutting surface.

7. The cannula as described in claim 1, whereas such cannula has side port located down the body of the trocar away from the cutting edge of the cannula, where the ports may be used to flow liquids to or from the insertion point of the cannula, and where the trocar described in claim 1, may be retracted away from the cutting edge, below the port, so as to allow the flow of liquids to or from the patient.

8. A hypodermic needle having a side port used to facilitate the flow of fluids into the body of a patient, and having a trocar that may be extended to be used to make the puncture of the patient, whereas such a trocar is used to block the flow of the fluids from the side port, but also have the necessary range of movement to withdraw the tip of the trocar past the port of fluid entry.

9. Where the trocar as described in claim 8, is not removable from the hypodermic needle.

10. Where the port as described in claim 8, is more than one port.

11. Where the port or ports, as described in claims 8 and 10, are used to introduce fluids into the patient.

12. Where the trocar described in claim 8, is within a sealed cavity within the hypodermic needle and at the point of extraction from the hypodermic cavity, there is a seal that keeps the fluids from seeping out through this exit in the hypodermic needle.

13. The hypodermic needle as described in claim 8, whereas the purpose of inducing the needle into the patient is for removal of fluids.

14. The trocar described in claim 8 and used in claim 13 to aid in entry of the hypodermic needle into the patient, whereas that trocar maybe withdrawn past the now exit port or ports allowing the fluids to flow from the patient through the exit port or ports.

15. Where the trocar as described in claim 8, is used in conjunction with a catheter in the manner described in claims 8-14, used to flow fluids into the patient.

16.Where the trocar as described in claim 8, is used in conjunction with a catheter in the manner described in claims 8-14, used to remove liquids from a patient.

17. Where the trocar, as described in claim 8, is used in conjunction with a cannula in the manner described in claims 8-14, used to flow fluids into the patient.

18. Where the trocar, as described in claim 8, is used in conjunction with a cannula in the manner described in claims 8-14, used to remove liquids from a patient.

19. Where the trocar described in claim 8, can be secured in the extended position by a mechanical means.

20. Where the trocar as described in claim 7, is not removable from the hypodermic needle.

21. Where the port as described in claim 7, is more than one port.

22. Where the port or ports, as described in claims 7 and 21, are used to introduce fluids into the patient.

23. Where the trocar described in claim 7, is within a sealed cavity within the hypodermic needle and at the point of extraction from the hypodermic cavity, there is a seal that keeps the fluids from seeping out through this exit in the hypodermic needle.

24. The cannula and trocar as described in claim 7, whereas the purpose of inducing the needle into the patient is for removal of fluids.

25. The trocar described in claim 7, whereas that trocar maybe withdrawn past the now exit port or ports allowing the fluids to flow from the patient through the exit port or ports.

26. Where the trocar as described in claim 7, is used in conjunction with a catheter is used used to flow fluids into the patient.

27. Where the trocar as described in claim 7, is used in conjunction with a catheter is used to remove liquids from a patient.

28. Where the trocar described in claim 8, can be secured in the extended position by a mechanical means.