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Primary Examiner: Dougherty; Sean P

Parent Case Text

CROSS-REFERENCE TO RELATED APPLICATIONS

The present invention and application relates to, and claims the benefit of the earlier filing date and priority of U.S. Provisional Patent Application No. 61/097,085 filed Sep. 15, 2008, for Lumbar Puncture Detection Device.

Claims

What is claimed is:

1. A device for withdrawing spinal fluid from or injecting fluid into a spinal canal, comprising: a solid trocar rod having a front tip with a beveled planar surface; a cannula comprising a shaft having a beveled patient end, a non-patient end, an outer surface, and a central passage adapted to receive said trocar rod; a depth marking on said shaft; and a first orientation marking on said shaft, wherein said first orientation marking indicates the

16. The device of claim 15 wherein each number indicates a measured distance between the number and the pointed tip of the bevel.

17. The device of claim 12 wherein the depth marking comprises a number.

18. The device of claim 17 wherein the device further comprises a plurality of depth markings wherein each depth marking comprises a number, and wherein the value of each number increases as the distance between the depth markings and the beveled patient end increases.

19. The device of claim 18 wherein each number indicates a measured distance between the number and the pointed tip of the bevel.

Description

FIELD OF THE INVENTION

The present invention relates to apparatus for detecting the accurate insertion of a lumbar puncture needle into a body part containing spinal fluid.

BACKGROUND OF THE INVENTION

The spinal canal contains fluid that bathes, feeds and protects the outer and innermost reaches of the nervous system. A spinal tap is a procedure which takes samples of a patient's cerebrospinal fluid (commonly called CSF). Spinal taps are performed when the physician suspects that the patient may have bleeding (such as subarachnoid hemorrhage, stroke) or an infection of the central nervous system (such as meningitis or encephalitis) or cancer within the nervous system. These procedures are often performed in the emergency room but can be performed in a doctor's office or in a hospital setting.

Before beginning a spinal tap procedure, the physician, or another medical professional, arranges the contents of a spinal tap "kit" on a tray next to where the physician will be sitting. The "kit" may consist of four sterile tubes, a spinal needle (with a stylet (also referred to as a trocar in the instant application) inserted through the spinal needle (also referred to as a cannula in the instant application), along with items for sterilizing the patient's skin and draping the patient.

For the procedure, the patient is asked to lie down in a curled-up position, exposing the back. The physician then sterilizes the patient's back and numbs the skin around the insertion point--a "sterile prep and drape." The physician then inserts a spinal needle, with a stylet inside the spinal needle, between the patient's lumbar (L) vertebrae (usually between the third and fourth (L3-4) or fourth and fifth (L4-5) vertebrae) and blindly advances the needle, with the stylet's beveled and pointed end extending from the end of the needle, through key ligaments until the needle has reached the fluid-filled area surrounding the patient's spine, the subdural/subarachnoid space. The stylet is used to prevent the tip of the spinal needle from becoming blocked by tissue as the needle passes through skin and other tissues or advancing skin cells into the spinal canal where a tumor may form. The stylet's beveled and pointed end may also assist penetration into the spinal ligaments by virtue of being pointed and sharp.

Once the needle is in place, and possibly rotated, the stylet is withdrawn from the spinal needle (cannula) and placed on the sterile tray. The operator must then wait (seconds to minutes) for the CSF to flow through the needle and drip from the proximal end of the needle. The physician looks at the fluid to make a visual determination if it is water-like `clear` or `blood-tinged` or another color. He then takes four sterile tubes in sequence from the tray and fills the tubes each with approximately 1 ml (1 cc) of CSF. Once collected, CSF is then sent to a laboratory to determine if the patient is suffering from viral, bacterial or fungal infection of the

both may be maintained in optimal parallel entry presentation to the ligaments if the orientation marking faces upward toward the physician's view.

The trocar 40 may include a patient end 42 with a beveled planar surface tip which is adapted to fit flush with the cannula beveled patient end 24, and a non-patient end 44 with a hub to apply insertion or withdrawal pressure to the trocar. The trocar 40 may be sized to fit relatively snugly within the central passage of the cannula 20, while still permitting the trocar to slide within the central passage. Some air space may exist between the central passage of the cannula 20 and the trocar 40 when the trocar is fully inserted. Preferably, the trocar 40 and the cannula 20 may be constructed of rigid material, such as surgical steel or plastic polymers, or the like which are known in the art. The trocar 40 is preferably sufficiently stiff and sharp to permit it to be inserted without damage through a patient's vertebral ligaments and withstand inadvertent insertion into bony vertebrae.

The venting members 28 (i.e., means for venting air) may be disposed in the windows 27 provided in the wall of the cannula 20. The venting members 28 may be sealed in the windows 27 such that fluid within the cannula central passage is prevented from escaping past or around the venting members. In the first embodiment of the present invention, the venting members 28 may be gas, and particularly air, permeable, but at least partially impermeable to a liquid, such as spinal fluid and blood. Preferably, the venting members 28 may be substantially porous for gas constituents less than about 5 microns in size, and substantially non-porous for liquid constituents about 5 microns and greater in size, however, it is appreciated that these approximate sizes should not be limiting for the invention.

The venting members 28 may be constructed of any of a number of materials that provide the desired level of porosity, which may include, but are not limited to sintered, layered, rolled, foamed, perforated, or impregnated, hydrophilic/hydrophobic compositions, porous polyethylene, porous polypropylene, porous polyfluorocarbon, absorbent paper, materials impregnated with dilute Russell Viper venom molded fiber, fiberglass, felt, granular starch, cellulose, polyacrylamide gel, hydrogel, a molded admixture of porous hydrophobic/hydrophilic granules and sufficiently low density silicone, molded open cell polyurethane, and like polymeric materials. Examples of materials that may be used to construct the venting (i.e., porous) members 28 are discussed in U.S. Pat. No. 4,207,870 to Eldridge, and U.S. Pat. No. 4,340,068 to Kaufman, each of which are hereby incorporated by reference. The venting members 28 may further comprise material which is rendered visibly darker or lighter when spinal fluid and/or blood is within the cannula.

The function of the first embodiment of the spinal fluid withdrawing device 10 will now be described with reference to FIGS. 4-5. With reference to FIG. 4, the trocar 40 and the cannula 20 may be pushed and/or bored into a patient's inter-vertebral spaces to a depth at which the physician expects the patient end 24 of the cannula may be in communication with the spinal canal and its spinal fluid. Once the cannula 20 is at such depth, the physician may begin to withdraw the trocar 40 out of the cannula 20. If no fluid is detected, the trocar 40 may be re-inserted and the device 10 may be pushed forward or pulled backward, depending upon the physician's belief as to the placement of the cannula 20. With reference to FIG. 5, as the trocar 40 is withdrawn, spinal fluid may flow from the patient 50 spinal canal 52 into the cannula 20 central passage. The spinal fluid may be more readily drawn into the cannula 20 central passage as a result of the venting members 28 permitting air to escape through them. Furthermore, the venting members 28 may be transparent or translucent such that the presence of spinal fluid and/or other bodily fluid such as blood may be visually detected by the physician. Such visual detection may be aided by directly bright light onto the venting members 28. Depending on the material selected for the venting members, it may be rendered visibly shaded (darker) or be clear or colored as is the spinal fluid.

A second embodiment of the present invention is illustrated in FIG. 6, in which like reference numerals refer to like elements discussed in the previous embodiments of the invention. With reference to FIG. 6, one or more of the windows 27 (and potentially all of the windows) may be provided with a transparent or translucent member 32 which does not act as a venting member. In such an embodiment, it is not necessary for the venting members 28 to be translucent or transparent or to change color in order to visually detect the presence of spinal fluid or other bodily fluids within the cannula 20. The transparent or translucent member 32 may be comprised of plastic or glass material which is suitable for medical applications. The cannula 20 may also be provided with an

orientation marking 30 and depth markings 26 in the same manner as in the first embodiment.

A third embodiment of the present invention is illustrated in FIG. 7, in which like reference numerals refer to like elements discussed in the previous embodiments of the invention. With reference to FIG. 7, the outer surface of the cannula 20 is provided with depth markings (e.g. in millimeters as in FIG. 7) 26 and an orientation marking 30. The trocar rod 40 is provided with an orientation marking 46. The depth markings 26 and orientation markings 30 and 46 may enable the physician to monitor and confirm both the depth and orientation of the bevel of the cannula patient end 24 and the beveled planar surface of the trocar 40 front tip during the lumber puncture procedure.

It will be apparent to those skilled in the art that variations and modifications of the present invention can be made without departing from the scope or spirit of the invention. For example, the shape, size, and material selection for the various components of the spinal fluid withdrawing device may be changed without departing from the intended scope of the invention and appended claims. It is further appreciated that forming one or more elements of the apparatus embodiments of the present invention integrally or separately is intended to fall within the scope of the invention and appended claims.

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