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(54) **INSERTION DEVICE FOR AN INSERTION
SET AND METHOD OF USING THE SAME**

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ABSTRACT

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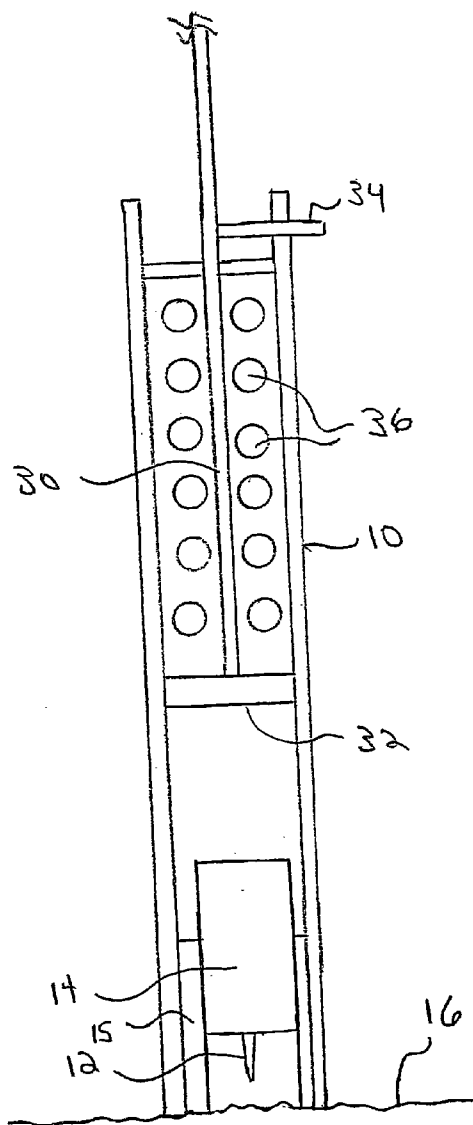
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A system for inserting at least a portion of an insertion set through the surface of a tissue, having: an inserter with a moveable plunger disposed within a cavity therein; an insertion set holder received into the distal end of the cavity; and an insertion set received into the insertion set holder, wherein the insertion set is moveable within the insertion set holder such that when the plunger is advanced into contact with the insertion set, the insertion set advances through the insertion set holder to a position at which at least a portion of the insertion set extends out of the distal end of the cavity.



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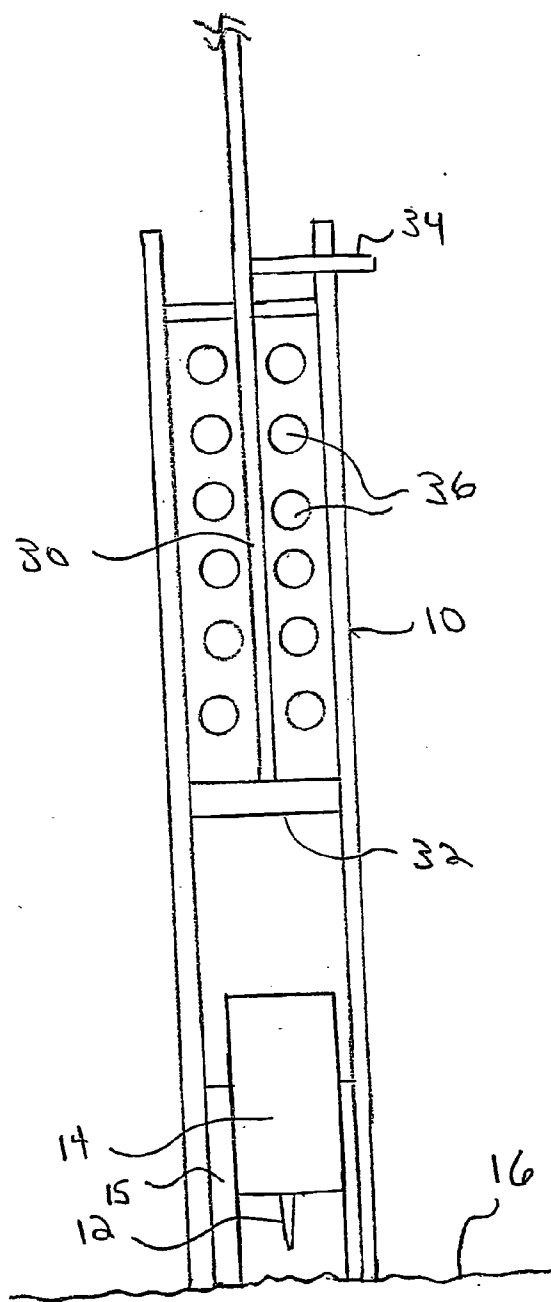


FIG 1A

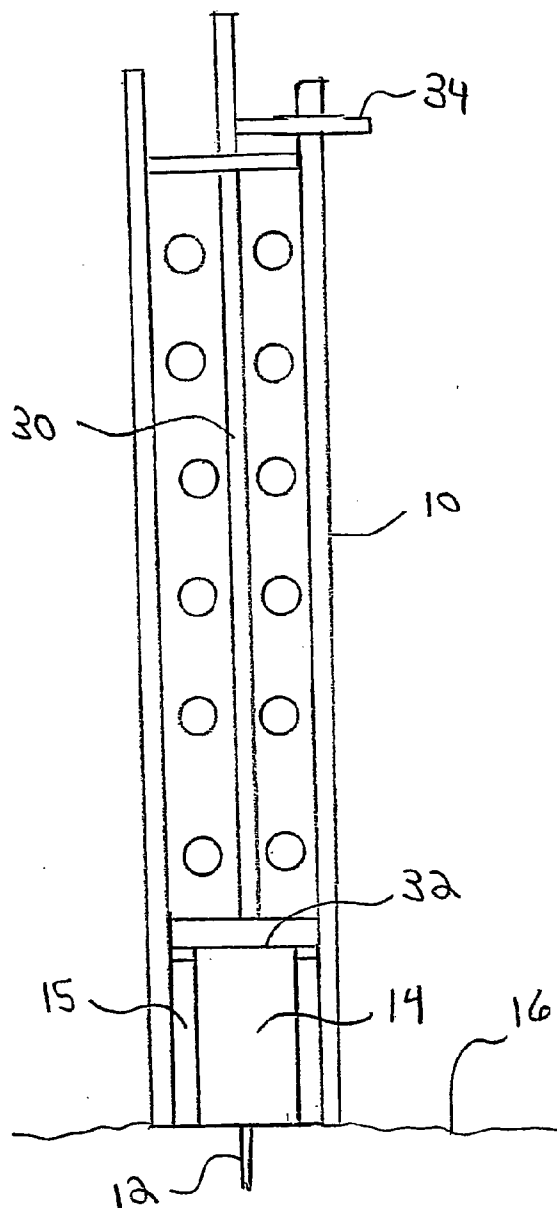


FIG 1B

FIG
2A

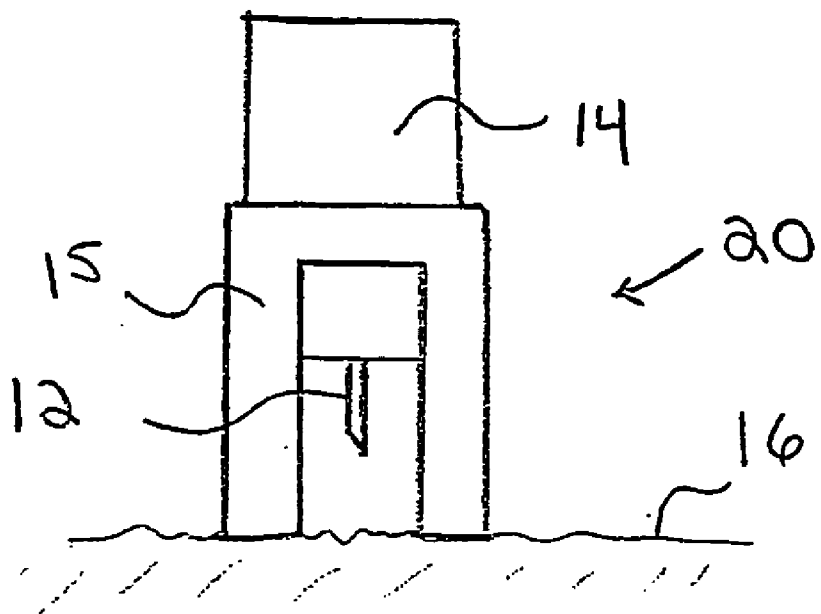
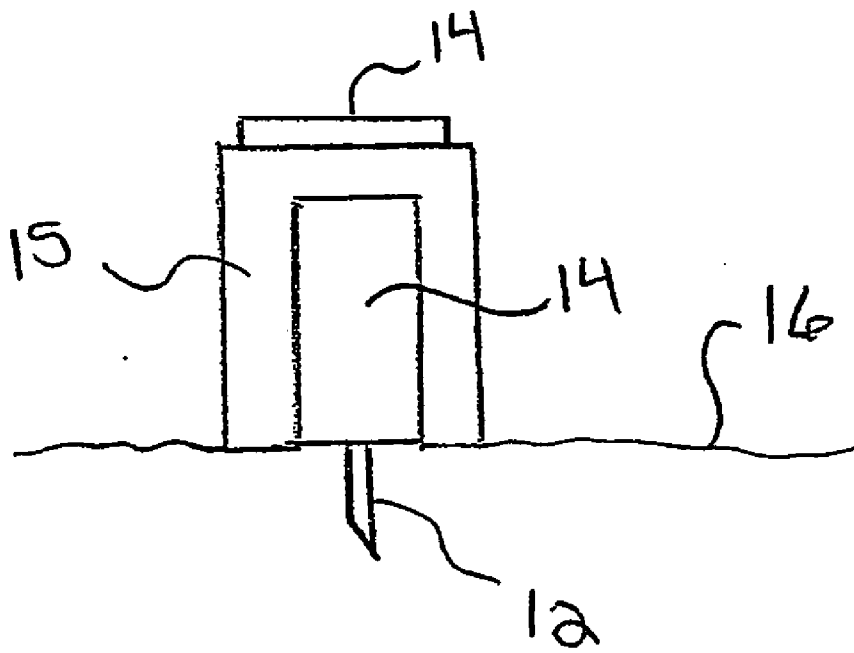


FIG
2B



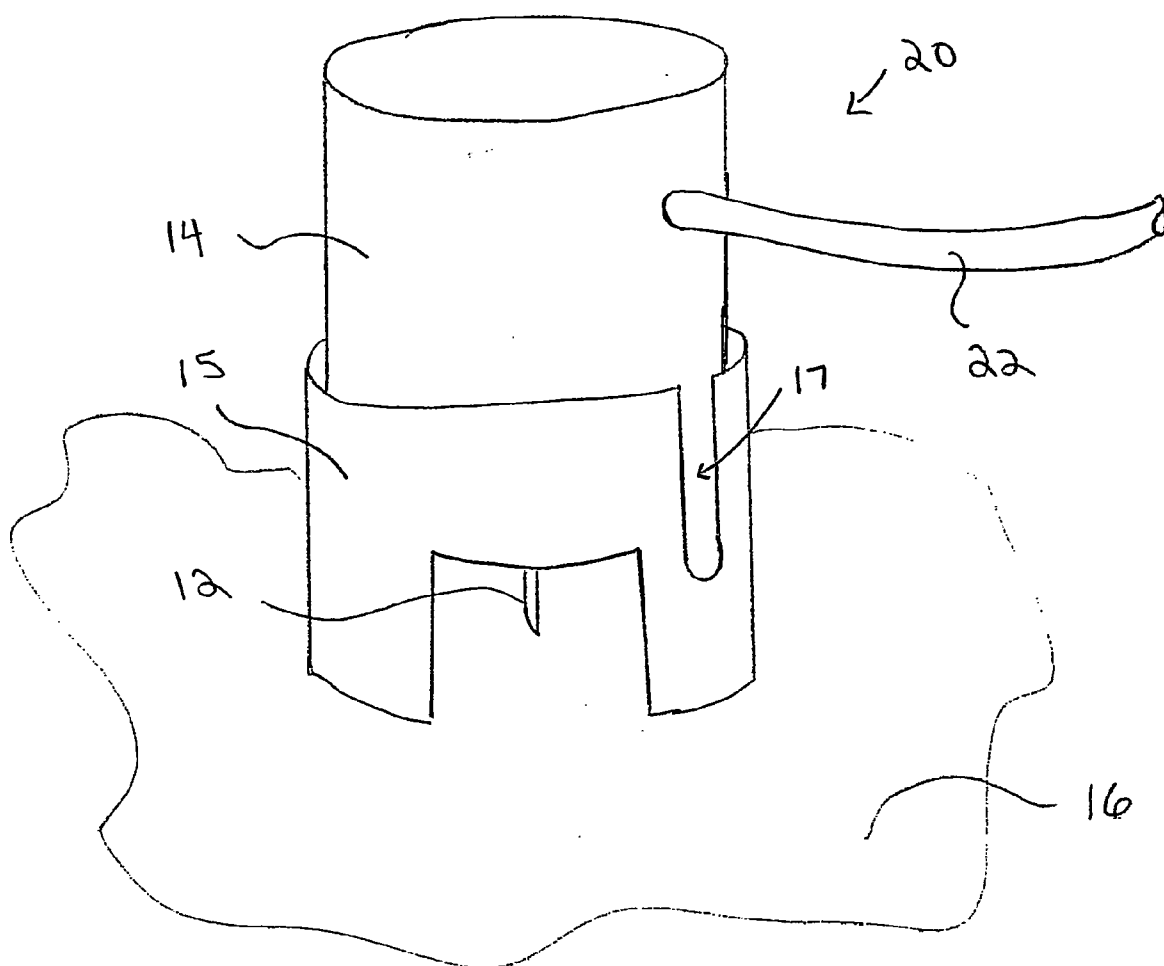


FIG 2c

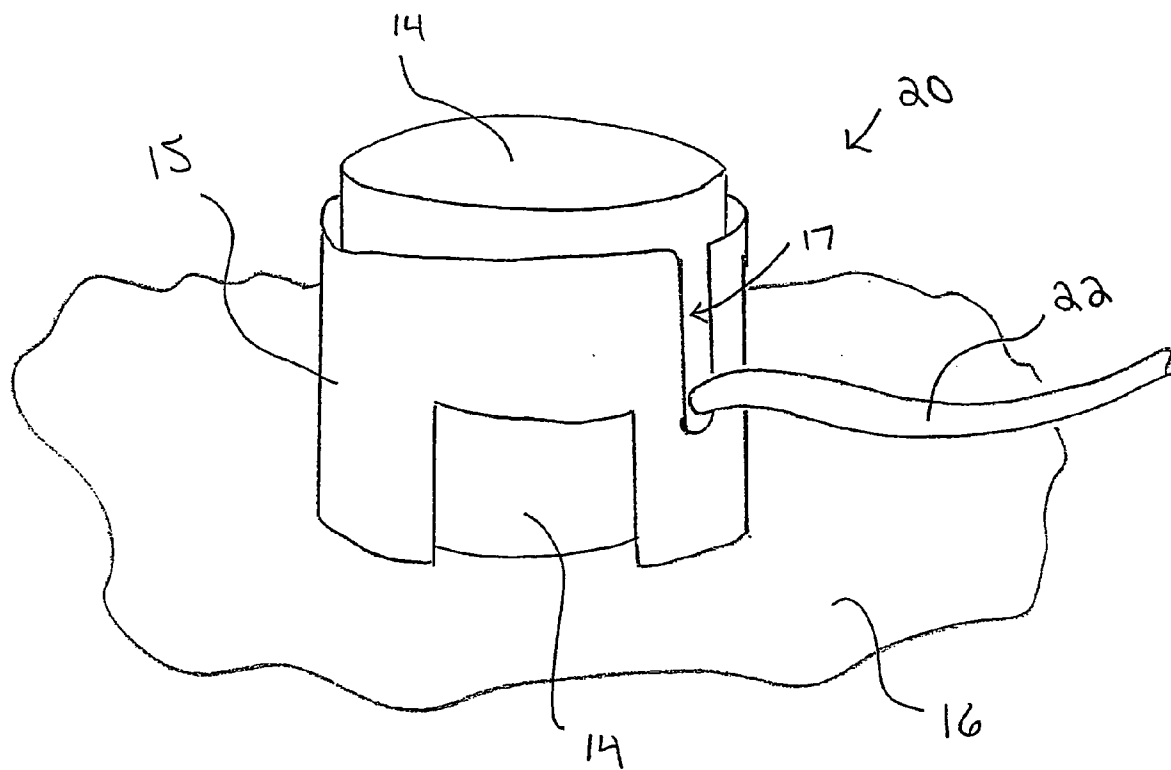


FIG 2D

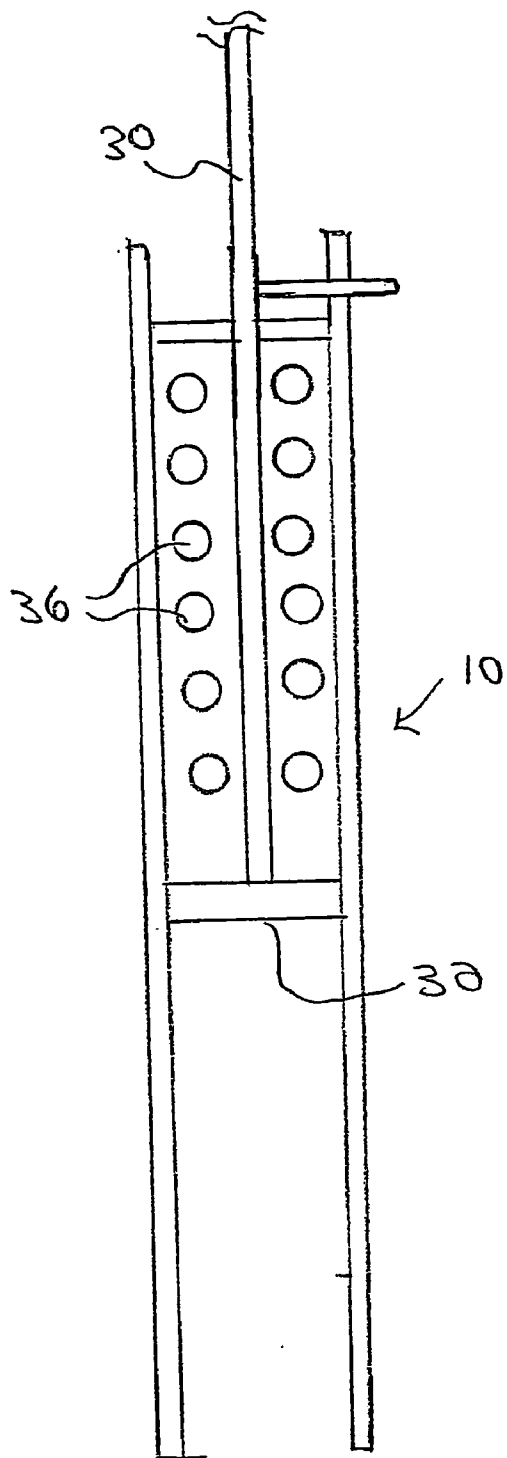


FIG 3A

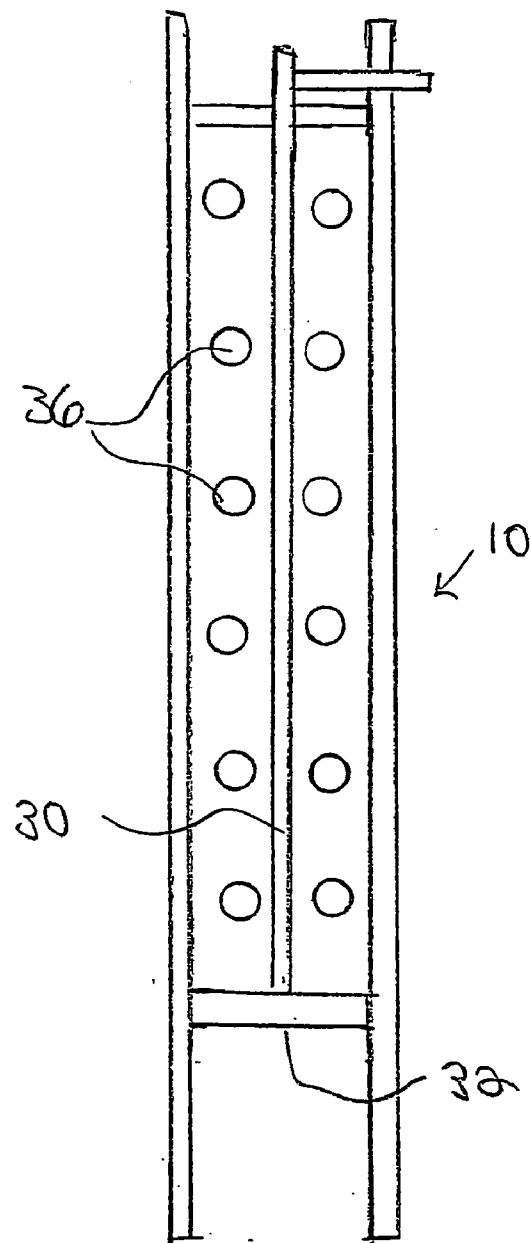


FIG 3B

INSERTION DEVICE FOR AN INSERTION SET AND METHOD OF USING THE SAME

TECHNICAL FIELD

[0001] The present invention is related to systems for placing various medical insertion sets (such as needles or infusion sets) into a patient's skin.

SUMMARY OF THE INVENTION

[0002] In various aspects, the present invention provides a system for inserting at least a portion of an insertion set through the surface of a tissue, comprising: an inserter with a moveable plunger disposed within a cavity therein; and an insertion set holder received into the distal end of the cavity; and an insertion set received into the insertion set holder, wherein the insertion set is moveable within the insertion set holder such that when the plunger is advanced into contact with the insertion set, the insertion set advances through the insertion set holder to a position at which at least a portion of the insertion set extends out of the distal end of the cavity.

[0003] In various aspects, the holder is held at a fixed position at the distal end of the of the cavity, but may easily be removed from the distal end of the cavity when the plunger has been advanced.

[0004] In other aspects of the invention, the present invention provides an inserter for inserting at least a portion of an insertion set through the surface of a tissue, comprising: a housing having a cavity therein, wherein the distal end of the cavity is adapted to receive a holder for an insertion set therein, the holder being adapted for slidable motion of the insertion set therein; and a moveable plunger disposed within the cavity for advancing the insertion set within the holder, wherein the plunger is moveable from a proximal position away from the insertion set to a distal position in contact with the insertion set.

[0005] In other aspects of the invention, the present invention provides an insertion set, comprising: a housing; a piercing member extending from the housing; and a holder, wherein the housing is slidably moveable within the holder from a first position at which a portion of the housing extends out of the holder and the piercing member does not extend out of the holder to a second position at which the piercing member extends out of the holder.

[0006] In various embodiments of the invention, the insertion set can be used with the present inserter, by itself, or with an adapter. Such adapter may include, but is not limited to, adapters as described in co-owned U.S. Provisional Patent Applications 60/407,531, filed Aug. 30, 2002 and 60/409,119, filed Sep. 9, 2002.

[0007] In other aspects of the invention, the present invention provides a holder for an insertion set, the insertion set having a housing with a piercing member extending therefrom, the holder being dimensioned such that the housing is slidably moveable within the holder from a first position at which a portion of the housing extends out of the holder and the piercing member does not extend out of the holder to a second position at which the piercing member extends out of the holder.

[0008] In accordance with the present invention, a novel inserter is used to insert a piercing member of a novel

insertion set into a patient. Together, the novel inserter and the novel insertion set are used in a novel system for inserting at least a portion of an the insertion set (e.g.: a piercing member of the insertion set) into a patient.

[0009] An advantage of the present invention is that it provides a simple, yet firm and stable system for inserting a needle or other piercing member(s) into a patient. In addition, the present invention provides a system for inserting a needle or other piercing member(s) into a patient at any angle to the patient's skin (i.e.: between 0 and 90 degrees).

[0010] According to an embodiment of the invention, an inserter is provided for quick and easy transcutaneous placement of a medical needle through the skin of a patient, particularly such as an insertion of a subcutaneous insertion set. The inserter is designed to place the needle through the skin at a selected insertion angle and with a controlled force and speed of insertion, to ensure proper needle placement with minimal patient discomfort. The inserter may preferably be designed to meet these objectives, while safeguarding against undesired projection of the medical needle through free space, in the event that the inserter is actuated in spaced relation to the patient's skin.

[0011] The inserter preferably comprises a spring-loaded plunger having a head for exerting force on a housing of an insertion set. The housing is designed for receiving and supporting the insertion set within an associated holder at a fixed location within the distal end of the inserter. When the plunger is advanced, it contacts the housing of the insertion set, and moves the housing of the insertion set (through the holder) to a position at which a needle (or other piercing member(s)) of the insertion set projects outwardly from the distal end of the inserter. Therefore, when the device is positioned against the patient's skin, and the plunger is advanced, the needle (or other piercing member(s)) of the insertion set projects through the patient's skin.

[0012] Thereafter, the inserter is removed, leaving behind the insertion set (and its associated holder) on the patient's skin. Thereafter, the holder is manually removed, leaving only the insertion set on the patient's skin, with the piercing member penetrating through the surface of the patient's skin.

[0013] In optional aspects, the plunger is designed for retraction and retention within a barrel to a cocked position with a drive spring compressed in a manner applying a predetermined spring force to the plunger head. A front or nose end of the inserter cavity or barrel is designed for attachment to the holder and the holder may be designed to be pressed placement against the skin of a patient, at a selected needle insertion site, and in an orientation with the needle disposed at a correct or desired insertion angle. A trigger member is operable to release the plunger and thereby permit the drive spring to carry the plunger toward the patient's skin with a controlled force and speed, thereby pushing the housing of the insertion set thereby resulting in proper transcutaneous placement of the insertion needle with minimal patient discomfort.

[0014] An advantage of the inserter design is that it does not require a return spring. (i.e.: a separate spring is not required for "arming" the inserter. Rather, the operator simply pulls the plunger upward to a retracted position prior to use.

[0015] The plunger head may optionally include a safety lock mechanism to retain the insertion set against projection from the inserter barrel. According to an embodiment, the safety lock mechanism comprises at least one safety lock arm(s) for engaging and retaining the insertion set when the plunger is retracted from a fully advanced position. Each safety lock arm may optionally include a cam lobe for engaging an appropriately shaped recess on the insertion set to prevent release thereof from the plunger head, unless and until the plunger head is returned to the fully advanced position. In such fully advanced position, the shape of the cam lobe may permit quick and easy separation of the inserter from the insertion set with a minimal separation force.

[0016] In operation, the safety lock arms thus prevent projection of the housing and the insertion set from the inserter, in the event that the trigger member is actuated with the nose end of the barrel of the inserter spaced from the skin of a patient. In that event, the plunger head is advanced with the controlled force and speed to the fully advanced position, but the insertion set is not thrown from the inserter as a projectile. Instead, the housing of the insertion set travels rapidly when impacted by the plunger head moving from a retracted position to a fully advanced position.

[0017] In other optional embodiments, the safety lock mechanism comprises a plunger head having a cylindrical shape defining a forwardly open cavity for receiving and supporting an insertion set (and its associated holder) with the insertion needle projecting outwardly. In this embodiment, the plunger head may include a radially inwardly projecting rim at a forward or nose end thereof, wherein the rim defines an oval-shaped opening. The size of the rim opening may permit relatively free reception of a hub on the insertion set, with the insertion set oriented at an angle relative to a central axis of the plunger head and barrel. The insertion set may then be reoriented to align the insertion needle coaxially with the central axis of the barrel and plunger head while being captivated in the body of the holder, so that the holder is received into a recess and is retained against undesired release from the inserter during spring-driven placement of the needle. After needle placement, the inserter may be released from the insertion set with minimal separation force by orienting the inserter angularly relative to the insertion set to permit free slide out passage of the hub through the oval rim opening.

[0018] In other optional embodiments of the present invention, the insertion set holder also includes a receiving structure to support the insertion set in a position with the at least one piercing member oriented for insertion through the skin of the patient at a predetermined angle relative to the skin of the patient upon movement of the plunger from the retracted position to the advanced position. As will be explained, this holder is manually separable from the housing of the insertion set. The plunger or other suitable driver is operatively coupled to the housing and the housing is oriented such that the plunger will urge the housing of the insertion set with a controlled force and speed from the retracted position toward the advanced position to place at least a portion of the at least one piercing member of the insertion set thorough the skin of the patient to install the insertion set to the patient. The insertion set holder is removable from the insertion set while maintaining the installation of the insertion set to the patient.

[0019] In particular embodiments, the predetermined angle relative to the skin is about 90 degrees, between 90 degrees and 10 degrees, or is after insertion between 0 and 10 degrees. In additional embodiments, the insertion set is a transcutaneous insertion set, a subcutaneous insertion set, an infusion set, sensor set or the like. In still other embodiments, the insertion set rests mainly on the surface of the skin after insertion or the insertion set is implanted in the skin of the patient. According to the invention's embodiments, the at least one piercing member is a needle. In alternative embodiments, the at least one piercing member is a plurality of needles, and can also be a plurality of micro-needles. Also, in some embodiments, the insertion set insertion set can be both an infusion set and a sensor set combined into an integral unit.

[0020] In yet other optional embodiments, the insertion set holder has a forward end defining a generally planar angled insertion contact surface for placement against the skin of a patient with the holder in a predetermined orientation relative to the patient's skin that mirrors the predetermined angle relative to the skin of the patient. Other embodiments include a trigger mechanism that actuates the driver. For instance, the trigger mechanism includes at least one trigger for fingertip depression to actuate the driver for movement of the insertion set housing (through the insertion set holder) from the retracted position to the advanced position. In addition, the plunger/driver can include at least one spring for spring-loaded movement of the plunger head used to urge the plunger body from the retracted position to the advanced position. Further, the plunger/driver can include a force changing mechanism that permits alteration of the controlled force and speed of the insertion set housing moving from the retracted position to the advanced position. In still further embodiments, the insertion set housing and its associated holder include a cooperatively engageable track mechanism for guiding movement of the housing between the advanced and retracted positions while retaining the housing against rotation relative to the inserter holder.

[0021] In additional optional embodiments of the insertion set, the at least one piercing member is provided with a piercing member hub. In addition, the receiving structure of the insertion set holder may include a recess formed therein for mated slide-fit reception of the piercing member hub of the insertion set. Further, the recess of the receiving structure can include a laterally open undercut recess. Alternatively, the receiving structure may include a safety retainer structure that retains the at least one piercing member on the receiving structure during movement from the retracted position to the advanced position. This safety retainer structure permits separation of the at least one piercing member from the plunger body when the plunger body is in the advanced position.

[0022] In optional embodiments of the insertion set, the set housing is coupled to the at least one piercing member. Also, the set housing is shaped to fit within the holder to orient the at least one piercing member for placement through the skin of the patient of at least a portion of the at least one piercing member at a predetermined angle relative to the skin of the patient to install the insertion set to the patient. The set housing of the insertion set is removable from the receiving structure of the inserter while maintaining the installation of the insertion set to the patient.

[0023] In particular embodiments of the insertion set, the predetermined angle relative to the skin is about 90 degrees, between 90 degrees and 10 degrees, or is after insertion between 0 and 10 degrees. In additional embodiments, the insertion set is a transcutaneous insertion set, a subcutaneous insertion set, an infusion set, sensor set or the like. In still other embodiments, the insertion set rests mainly on the surface of the skin after insertion or the insertion set is implanted in the skin of the patient. According to various embodiments, the at least one piercing member is a needle. In alternative embodiments, the at least one piercing member is a plurality of needles, and can also be a plurality of micro-needles. Also, in some embodiments, the insertion set can be both an infusion set and a sensor set combined into an integral unit.

[0024] Other features and advantages of the invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings which illustrate, by way of example, various features of embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] FIG. 1A shows a sectional side elevation view of an inserter with an insertion set received in its distal end prior to positioning the insertion set in a patient.

[0026] FIG. 1B shows the system of FIG. 1A after a plunger has been advanced in the inserter, thereby sliding the insertion set through its associated housing such that a piercing needle of the insertion set has been deployed into a patient.

[0027] FIG. 2A is a side elevation view of the insertion set and its associated holder prior to needle deployment.

[0028] FIG. 2B is a side elevation view of the insertion set and its associated holder after needle deployment.

[0029] FIG. 2C is a perspective view corresponding to FIG. 2A.

[0030] FIG. 2D is a perspective view corresponding to FIG. 2B.

[0031] FIG. 3A shows the inserter prior to deployment.

[0032] FIG. 3B shows the inserter after its deployment.

DETAILED DESCRIPTION OF THE INVENTION

[0033] The present invention may be understood more readily by reference to the following detailed description of the various embodiments of the invention and the Figures.

[0034] Before the present articles and methods are disclosed and described, it is to be understood that the terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting. It must be noted that, as used in the specification and the appended claims, the singular forms "a", "an" and "the" include plural referents unless the context clearly dictates otherwise.

[0035] As shown in the drawings for purposes of illustration, the invention is embodied in a system comprising an inserter, an insertion set holder and an insertion set. In various embodiments, the insertion sets may comprise any form of infusion set, sensor set, medical device, or the like.

Further embodiments of the present invention may be used to insert other insertion sets or medical devices such as biodegradable implants, capsules, impregnated threads (with medications or the like). Other insertion sets may be directed to a threaded needle insertion set, such as that described in U.S. Pat. No. 5,584,813 issued Dec. 17, 1996 to Livingston et al. entitled "Subcutaneous Injection Set" and U.S. Pat. No. 5,779,665 issued on Jul. 14, 1998 to Mastrototaro et al. entitled "Transdermal Introducer Assembly", which are herein incorporated by reference. In addition, the insertion sets may be coated with medications, or other agents, that inhibit infection and/or promote healing of the insertion site. Various embodiments of the invention include insertion sets for transcutaneous placement in subcutaneous tissue. However, according to various embodiments, the insertion set may be inserted into other subdermal tissues. In addition, still further embodiments may be used to place the sets in other types tissue, such as muscle, lymph, organ tissue or the like, and used in animal tissue.

[0036] According to the embodiments of the present invention, the inserter and insertion set holder is loaded with a standard hand-held insertion set, or the like, and then placed against the skin of the user, where the insertion device and plunger is activated to transcutaneously place a portion of the insertion set, or the like, subcutaneously in a quick manner that minimizes pain and/or discomfort to the user. However, it will be recognized that further embodiments of the invention may be used to place an entire insertion set, or the like, beneath the skin, rather than just a portion of the insertion set. As discussed, embodiments of the insertion device and plunger are designed to accommodate off-the-shelf insertion sets, or the like. But, alternative embodiments may be used with customized insertion sets, or the like that have been altered to fit the insertion device and plunger in a particular orientation or configuration to improve safety and/or assure proper placement of the insertion set, or the like. In still other embodiments, the insertion sets, or the like may be angled and the devices are capable of insertion at angles between 0 and 90 degrees relative to the skin surface after insertion of the insertion set.

[0037] According to embodiments of the present invention, the insertion set includes at least one piercing member to pierce the skin during insertion. In particular embodiments, the piercing member is a metal needle. In alternative embodiments, the needle may be hollow, solid, half needle (or other fraction), or the like. In further alternative embodiments, the piercing member may be made out of other materials, such as ceramic, plastic, composites, silicon micro-needles, biodegradable, hydrophilic substances, substances that soften and/or change once in contact with the body and/or bodily fluids, or the like. In other alternative embodiments, the insertion set may include more than one piercing member. For example, a single insertion set may include a piercing member for an infusion portion and another piercing member for a separate sensor portion, or the like. Alternatively, the insertion set may include a plurality of small piercing members on a small patch or substrate, such as a series of hollow micro-needles (such as from silicon, plastics, metal or the like) for infusion of a medication or a series of solid micro-needles for sensor applications (such as from silicon, plastics, metal or the like), which micro-needles are used to penetrate the skin.

[0038] As shown in the exemplary drawings, an inserter in accordance with a first embodiment of the present invention is referred to generally by the reference numeral **10** is provided for quick and easy transcutaneous placement of a medical needle, particularly such as an insertion needle **12** of the type provided with a subcutaneous insertion set **14** as depicted in **FIGS. 2A to 2D**. The inserter **10** may include a trigger-type actuator mechanism for transcutaneous placement of the insertion needle **12** with a controlled speed and force, and with the insertion needle **12** oriented at a desired angular position relative to the skin **16** of the patient.

[0039] Inserter **10** of the present invention, as shown in the illustrative drawings, is particularly designed for placement of the insertion needle **12** of a subcutaneous insertion set **14**, such as an insertion set of the general type shown and described in U.S. Pat. Nos. 4,755,173; 5,176,662; and 5,257,980, which are incorporated by reference herein. Such insertion sets **14** are used to infuse medical fluids such as selected medications to a patient, with one example being the administration of insulin to a diabetic by operation of a programmable medication infusion pump (not shown) of the type described in U.S. Pat. No. 4,685,903. Alternatively, the inserter **10** may be used to transcutaneously place a medical needle associated with other types of insertion sets, such as transcutaneous sensor insertion sets of the general type shown and described in U.S. Pat. Nos. 5,390,671; 5,560,806 and 5,586,553, which are also incorporated by reference herein. Such insertion sets are used, for example, to monitoring patient glucose levels.

[0040] **FIG. 1A** shows inserter **10** supporting an insertion set holder **15** within its distal end. An insertion set **14** is slidably received within holder **15**. Inserter **10** has a hollow cavity in which plunger **30** is disposed. When plunger **30** is moved from the position in **FIG. 1A** to the position in **FIG. 1B**, plunger head **32** pushes against body **14** of insertion set **20**, thereby moving body **14** such that needle **12** penetrates the patient's skin **16**.

[0041] In accordance with the present invention, body **14** of insertion set **20** is slidably moveable within insertion set holder **15**. Holder **15** can be manually separated from housing **14**. This is seen most clearly in **FIGS. 2A to 2D** where the insertion set **20** (including housing **14**, needle **12** and holder **15**) is initially positioned as shown in **FIGS. 2A and 2C** when received into the distal end of the cavity or barrel of inserter **10**. After plunger **30** has been advanced, plunger head **32** will advance body **14** through holder **15** such that needle **12** penetrates the patient's skin **16**.

[0042] In further optional aspects of the invention, insertion set **20** may include infusion tubing **22** to permit medication delivery (through needle **12**) into the patient. As can also be seen in **FIGS. 2C and 2D**, holder **15** may include a slot **17** in which tubing **22** is free to travel. Body **14** may further comprise an internal chamber (not shown) for receiving medication via infusion tubing **22**. Body **14** of insertion set **20** may further comprise a large winged base (not shown) through which needle **12** extends. The bottom surface of the winged base may have an adhesive covering (with a peel-away covering) to assist in affixing body **14** to the patient's skin.

[0043] The inserter **10** of the present invention represents a simple device which can be used by the patient to quickly and easily place the subcutaneous insertion set **20** in a proper

transcutaneous position and orientation, at a selected medication insertion site. The inserter **10** is preferably designed to project the insertion set toward the patient's skin **16** at a controlled force and speed for quickly piercing the skin in a manner insuring proper placement of the insertion needle **12**, while minimizing patient anxiety and/or discomfort. Improper and/or partial placement of the insertion needle **12** is thus avoided.

[0044] As shown in **FIG. 1A and 1B**, holder **15** is received into the distal end of inserter **10**. Holder **15** preferably remains in the same position in inserter **10** as housing **14** (and needle **12**) are advanced by plunger **30**. After the present invention has been deployed, inserter **10** is then removed, leaving holder **15** and insertion set body **14** sitting on the patient's skin. Thereafter, the patient simply pulls holder **15** away from insertion set body **14**. Thus, after deployment, insertion set body **14** remains sitting on the patient's skin (with associated needle **12** penetrating into the patient's skin).

[0045] The plunger **30** of inserter **10** is preferably driven downward by springs **36** (shown in sectional view). A trigger **34** may be used to release spring **36** so that plunger **30** moves downward from the position of **FIGS. 1A/3A** to that of **1B/3B**.

[0046] Preferably, trigger **34** (or other suitable driver actuator such as air, spring or solenoid valve) is adapted to hold the plunger **30** in a retracted position, against the force of a compressed drive spring **36**. Fingertip depression of trigger **34** releases plunger **30** for spring-loaded travel toward the advanced position.

[0047] In optional aspects, the body **14** and holder **15** of insertion set **20** are designed such that the system is biased to move to the position shown in **FIGS. 2A/2C**. This is particularly advantageous in avoiding needle contact when the operator is loading insertion set **20** into the distal end of the barrel of inserter **10**. In this aspect of the invention, the downward force of plunger **30** (when spring **36** is released by trigger **34**) will overcome the internal biasing of insertion set **20**, instead moving it to the deployed position shown in **FIGS. 2B and 2D**.

[0048] The foregoing embodiments and advantages are merely exemplary and are not to be construed as limiting the present invention. The present teaching can be readily applied to other types of devices and applications that may be common to those of ordinary skill in the art. The description of the present invention is intended to be illustrative, and not to limit the scope of the claims. Many alternatives, modifications, and variations will be apparent to those skilled in the art.

What is claimed is:

1. An inserter for inserting at least a portion of an insertion set through the surface of a tissue, comprising:

- a housing having a cavity therein, wherein the distal end of the cavity is adapted to receive a holder for an insertion set therein, the holder being adapted for slidable motion of the insertion set therein; and
- a moveable plunger disposed within the cavity for advancing the insertion set within the holder, wherein

the plunger is moveable from a proximal position away from the insertion set to a distal position in contact with the insertion set.

2. The inserter of claim 1, wherein the holder is removable from the distal end of the cavity.

3. The inserter of claim 1, wherein the distal end of the cavity is adapted to receive the holder in a fixed position thereat.

4. A system for inserting at least a portion of an insertion set through the surface of a tissue, comprising:

an inserter with a moveable plunger disposed within a cavity therein; and

an insertion set holder received into the distal end of the cavity; and

an insertion set received into the insertion set holder, wherein the insertion set is moveable within the insertion set holder such that when the plunger is advanced into contact with the insertion set, the insertion set advances through the insertion set holder to a position at which at least a portion of the insertion set extends out of the distal end of the cavity.

5. The device of claim 4, wherein the moveable plunger is spring-loaded.

6. The system of claim 4, wherein the holder is removable from the distal end of the cavity.

7. The device of claim 4, wherein the holder is held at a fixed position in the distal end of the cavity.

8. The system of claim 4, wherein the plunger is moveable from a proximal position away from the insertion set to a distal position in contact with the insertion set.

9. An insertion set, comprising:

a housing;

a piercing member extending from the housing; and

a holder, wherein the housing is slidably moveable within the holder from a first position at which a portion of the housing extends out of the holder and the piercing member does not extend out of the holder to a second position at which the piercing member extends out of the holder.

10. The system of claim 9, wherein the insertion set further comprises:

infusion tubing extending from the housing.

11. A holder for an insertion set, the insertion set having a housing with a piercing member extending therefrom, the holder being dimensioned such that the housing is slidably moveable within the holder from a first position at which a portion of the housing extends out of the holder and the piercing member does not extend out of the holder to a second position at which the piercing member extends out of the holder.

12. The inserter of claim 1, wherein the inserter does not have a return spring.

13. The insertion set of claim 9, wherein the housing holds the insertion set such that the piercing member of the insertion set is at an angle of between 10 and 90 degrees to the skin.

* * * * *