MICROINFUSER WITH AUTOMATIC NEEDLE RETRACTION

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention relates generally to a device for delivering a fluid into the body of a patient by injection and, more particularly, to an infusing device with a mechanism for automatically retracting a needle after injection.

Description of Related Art

[0002] Various types of automatic injection devices have been developed to allow drug solutions and other liquid therapeutic preparations to be administered by untrained personnel or to be self-injected. Generally, these devices include a reservoir that is pre-filled with the liquid therapeutic preparation, and some type of automatic needle-injection mechanism (usually of the spring-loaded type) that can be triggered by the user. When the volume of fluid or drug to be administered is generally below a certain volume, such as 1 mL, an auto injector is typically used, which typically has an injection time of about 10 to 15 seconds. When the volume of fluid or drug to be administered is above 1 mL, the injection time generally becomes longer resulting in difficulties for the patient to maintain contact between the device and the target area of the patient's skin. Further, as the volume of drug to be administered becomes larger, increasing the time period for injection becomes desirable. The traditional method for a drug to be injected slowly into a patient is to initiate an IV and inject the drug into the patient's body slowly. Such a procedure is typically performed in a hospital or outpatient setting.

[0003] Certain devices allow for self-injection in a home setting and are capable of gradually infusing a liquid therapeutic preparation into the skin of a patient. In some cases, these devices are small enough (both in height and in overall size) to allow them to be "worn" by a patient while the liquid therapeutic preparation is being infused into the patient. These devices typically include a pump or other type of discharge mechanism to force the liquid therapeutic preparation to flow out of a reservoir and into the injection or infusion needle. Such devices also typically include a valve or flow control mechanism to cause the liquid therapeutic preparation to begin to flow at the proper time and a triggering mechanism to initiate the injection. As with conventional syringes, needle-stick injuries with self-injection infusing devices are a concern.

SUMMARY OF THE INVENTION

[0003a] In one aspect, the present invention presents a device for delivering a fluid comprising: a housing defining an interior space and having a bottom surface configured for contacting a patient, the bottom surface defining a needle opening;

a reservoir disposed within the interior space of the housing for containing a fluid therein;

a needle carrier disposed within the housing;

an injection needle supported by the needle carrier and defining a lumen, the lumen of the injection needle configured to be placed in fluid communication with the reservoir, wherein the injection needle is transitionable from an initial position in which the injection needle is disposed within the housing, to a use position in which the injection needle extends through the needle opening, and a substantially shielded position in which the injection needle is disposed within the housing;

a needle actuator controlling positioning of the needle carrier and the injection needle; and

an indicator for separately indicating when the injection needle is in the initial position, the use position, and the shielded position;

wherein the indicator comprises an indicator tab disposed on and movable with the needle actuator and the needle actuator closes the needle opening when the injection needle is in the shielded position

[0004] In one example, a device for delivering a fluid includes a housing defining an interior space and having a bottom surface configured for contacting a patient. The bottom surface defines a needle opening. The device also includes a reservoir disposed within the interior space of the housing for containing a fluid therein, a needle carrier disposed within the housing, and an injection needle supported by the needle carrier and defining a lumen. The lumen of the injection needle is configured to be placed in fluid communication with the reservoir. The injection needle is transitionable from an initial position in which the injection needle is disposed within the housing, to a use position in which the injection needle extends through the needle opening, and a substantially shielded position in which the injection needle is disposed within the housing and the lumen of the needle is blocked by a portion of the housing.

[0005] The device may also include a needle actuator having a first ramp portion having an inclined section and a level section with the level section being generally parallel to the

bottom surface of the housing. The needle carrier may include a first engagement for contacting the inclined section of the first ramp portion to transition the injection needle from the initial position to the use position. The needle actuator may also include a second ramp portion having an inclined section and a level section being generally parallel to the bottom surface of the housing and the needle carrier may include a second engagement for contacting the inclined section of the second ramp portion to transition the injection needle from the use position to the shielded position. The device may include a pad disposed within the housing, where the lumen of the injection needle is blocked by the pad when the injection needle is in the shielded position. The needle actuator may be configured to drive the injection needle into the pad when the injection needle is transitioned from the use position to the shielded position. At least a portion of the pad may be received by the needle actuator in the shielded position.

[0006] The reservoir may be configured to automatically supply fluid to the injection needle after the injection needle is transitioned from the initial position to the use position. A needle actuator may be configured to engage the needle carrier to transition the injection needle from the initial position, to the use position, and the shielded position. The reservoir may comprise a syringe assembly including a syringe barrel for containing a fluid therein, a stopper disposed within the syringe barrel, and a plunger configured to advance the stopper within the syringe barrel to expel the fluid therefrom. The device may include a plunger stop

engaged with the plunger when the injection needle is in the initial position, wherein the plunger stop is configured to engage the needle carrier and release the plunger stop from the plunger when the injection needle is transitioned from the initial position to the use position. The device may include a needle stop configured to restrict movement of the injection needle from the use position to the shielded position until a predetermined amount of fluid has been dispensed from the reservoir. The needle stop may include a rotatable body which engages the needle actuator and the plunger when the injection needle is in the use position with the needle stop disengaging from the plunger when the injection needle is transitioned from the use position to the shielded position.

[0007] The device may also include an activation button, wherein deployment of the activation button allows the injection needle to transition from the initial position to the use position. The device may be provided with an indicator for indicating when the injection needle is in the initial position, the use position, and the shielded position.

[0008] In a further example, a device for delivering a fluid includes a housing defining an interior space and having a bottom surface configured for contacting a patient. The bottom surface defines a needle opening. The device further includes a reservoir disposed within the interior space of the housing for containing a fluid therein, a needle carrier disposed within the housing, and an injection needle supported by the needle carrier and defining a lumen. The lumen of the injection needle is configured to be placed in fluid communication with the reservoir, wherein the injection needle is transitionable from an initial position in which the injection needle is disposed within the housing, to a use position in which the injection needle extends through the needle opening, and a substantially shielded position in which the injection needle is disposed within the housing. The device also includes an indicator for indicating when the injection needle is in the initial position, the use position, and the shielded position.

[0009] The housing may include at least one indicator lens, where the indicator is visible from an exterior of the housing via the indicator lens. The indicator may provide a visual and tactile indication of the position of the injection needle. The indicator may include an indicator post with the housing defining an indicator opening. The indicator post is disposed within the housing when the injection needle is in the initial position and the use position and extends through the indicator opening when the injection needle is in the shielded position.

[0010] In another example, a device for delivering a fluid includes a housing defining an interior space and having a bottom surface configured for contacting a patient. The

bottom surface defines a needle opening. The device further includes a reservoir disposed within the interior space of the housing for containing a fluid therein, a needle carrier disposed within the housing, an activation member, and an injection needle supported by the needle carrier and defining a lumen. The lumen of the injection needle is configured to be placed in fluid communication with the reservoir. Deployment of the activation member causes the injection needle to transition from an initial position in which the injection needle is disposed within the housing, to a use position in which the injection needle extends through the needle opening, and a substantially shielded position in which the injection needle is disposed within the housing.

[0011] The device may include a needle actuator configured to engage the needle carrier to transition the injection needle from the initial position, to the use position, and the shielded position. The device may also include a needle stop configured to restrict movement of the injection needle from the use position to the shielded position until a predetermined amount of fluid has been dispensed from the reservoir. The activation member may engage the needle actuator when the injection needle is in the initial position. The needle stop may engage the needle actuator when the injection needle is in the use position, and the needle stop may be disengaged from the needle actuator when the injection needle is in the shielded position.

[0012] Further details and advantages of the invention will become clear upon reading the following detailed description in conjunction with the accompanying drawing figures, wherein like parts are designated with like reference numerals throughout.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] **FIG. 1** is a perspective view of a device for delivering a fluid into a patient by injection in accordance with an embodiment of the present invention.

[0014] **FIG. 2** is a front view of the device of **FIG. 1** in accordance with an embodiment of the present invention.

[0015] **FIG. 3** is a right view of the device of **FIG. 1** in accordance with an embodiment of the present invention.

[0016] **FIG. 4** is a rear view of the device of **FIG. 1** in accordance with an embodiment of the present invention.

[0017] **FIG. 5** is a top view of the device of **FIG. 1** in accordance with an embodiment of the present invention.

[0018] **FIG. 6** is a left view of the device of **FIG. 1** in accordance with an embodiment of the present invention.

[0019] **FIG. 7** is a bottom view of the device of **FIG. 1** in accordance with an embodiment of the present invention.

[0020] **FIG. 8** is a bottom view of the device of **FIG. 1** showing a needle cap removed in accordance with an embodiment of the present invention.

[0021] **FIG. 9** is a perspective view of the device of **FIG. 1** showing a top cover removed in accordance with an embodiment of the present invention.

[0022] **FIG. 10** is a perspective view of the device of **FIG. 1** showing detail of an activation button in accordance with an embodiment of the present invention.

[0023] **FIG. 11** is a perspective view of an activation button in accordance with an embodiment of the present invention.

[0024] **FIG. 12** is a bottom view of the device of **FIG. 1** showing a bottom portion of the housing removed in accordance with an embodiment of the present invention.

[0025] **FIG. 13** is a perspective view of the device of **FIG. 1** showing a first position of a plunger stop in accordance with an embodiment of the present invention.

[0026] **FIG. 14** is an enlarged perspective view of the device of **FIG. 1** showing a second position of a plunger stop in accordance with an embodiment of the present invention.

[0027] **FIG. 15** is a partial perspective view of the device of **FIG. 1** showing a second position of a plunger stop in accordance with an embodiment of the present invention.

[0028] **FIG. 16** is a cross-sectional view taken along line **16-16** of **FIG. 10** in accordance with an embodiment of the present invention.

[0029] **FIG. 17** is a perspective view of a stopper in accordance with an embodiment of the present invention.

[0030] **FIG. 18** is a perspective view of a stopper in accordance with an embodiment of the present invention.

[0031] **FIG. 19** is a top view of the device of **FIG. 1** showing engagement between a needle stop and needle actuator in accordance with an embodiment of the present invention.

[0032] **FIG. 20** is a partial bottom view of the device of **FIG. 1** showing engagement between a needle stop and plunger in accordance with an embodiment of the present invention.

[0033] **FIG. 21** is a partial perspective view of the device of **FIG. 1** showing a needle actuator removed and a plunger in an extended position in accordance with an embodiment of the present invention.

[0034] **FIG. 22** is a partial top view of the device of **FIG. 1** showing a rotated position of a needle stop in accordance with an embodiment of the present invention.

[0035] **FIG. 23** is a top perspective view of the device of **FIG. 1** showing a use position of an injector needle in accordance with an embodiment of the present invention.

[0036] **FIG. 24** is a bottom perspective view of the device of **FIG. 1** showing a use position of an injector needle in accordance with an embodiment of the present invention.

[0037] **FIG. 25** is a perspective view of the device of **FIG. 1** showing an injector needle transitioning from a use position to a shielded position in accordance with an embodiment of the present invention.

[0038] **FIG. 26** is a perspective view of the device of **FIG. 1** showing an injector needle in a shielded position in accordance with an embodiment of the present invention.

[0039] **FIG. 27** is a partial perspective view of the device of **FIG. 1** showing an injector needle in a shielded position with a needle actuator removed in accordance with an embodiment of the present invention.

[0040] **FIG. 28** is a bottom view of the device of **FIG. 1** showing an injector needle in a shielded position in accordance with an embodiment of the present invention.

[0041] **FIG. 29** is a cross-sectional view of a needle actuator in accordance with an embodiment of the present invention.

[0042] **FIG. 30** is a schematic view of a needle carrier showing a pre-loaded position of the needle carrier just prior to movement of an injection needle to a use position in accordance with an embodiment of the present invention.

[0043] **FIG. 31** is a schematic view of a needle carrier showing a pre-loaded position of the needle carrier just prior to movement of an injection needle to a shielded position in accordance with an embodiment of the present invention.

[0044] **FIG. 32** is a top view of the device of **FIG. 1** showing a needle carrier removed in accordance with an embodiment of the present invention.

[0045] **FIG. 33** is a perspective view of a device for delivering a fluid into a patient by injection in accordance with a further embodiment of the present invention.

[0046] **FIG. 34** is a perspective view of the device of **FIG. 33** showing button lock in a second position in accordance with a further embodiment of the present invention.

[0047] **FIG. 35** is a perspective view of the device of **FIG. 33** showing a top cover removed in accordance with a further embodiment of the present invention.

[0048] **FIG. 36** is a perspective view of the device of **FIG. 33** showing the device at the end of an injection cycle in accordance with a further embodiment of the present invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

[0049] For purposes of the description hereinafter, spatial orientation terms, if used, shall relate to the referenced embodiment as it is oriented in the accompanying drawing figures or otherwise described in the following detailed description. However, it is to be understood that the embodiments described hereinafter may assume many alternative variations and embodiments. It is also to be understood that the specific devices illustrated in the accompanying drawing figures and described herein are simply exemplary and should not be considered as limiting.

[0050] Referring to **FIGS. 1-16**, a device for delivering a fluid into a patient by injection **10** is shown. The device **10** generally includes a housing **12** having a first end **14** and a second end **16**. The housing **12** includes a bottom portion **18** and a top cover **20** that define an interior space **22**. The device further includes a reservoir **26**, an injection needle **28**, a needle carrier **30**, a needle actuator **32**, a plunger stop **34**, a needle stop **36**, and an activation button **38** that are accommodated by the housing **12**. The device **10** is utilized to inject a drug or medicament into a patient and is configured to be engaged with, such as mounted onto, a patient's skin for self-administration. Any form of medicament, *e.g.*, liquid or slurry, including one or more pharmaceutically-active agents, may be administered by the device **10**.

[0051] Referring to **FIGS. 1-9**, the top cover **20** of the housing **12** includes a reservoir opening **44**, a button opening **46**, a first indicator lens **48**, a second indicator lens **50**, and third indicator lens **52**. The reservoir opening **44** allows for the visual inspection of the reservoir **26** without removing the top cover **20**. The button opening **46** receives the activation button **38** with a portion of the activation button **38** extending through the opening **46**. The first, second, and third indicator lenses **48, 50, 52** may allow visual inspection of a portion of the needle actuator **32** to provide an indication of the status of the device **10**. In particular, the first, second, and third indicator lenses **48, 50, 52** may be made from a transparent material to allow visual inspection of the interior space **22** of the housing **12**, as

will be described herein. The bottom portion **18** of the housing **12** has a bottom surface **54** that defines a needle opening **56**. The bottom surface **54** is configured to be placed into contact with a target surface (not shown) of a patient. As shown in **FIG. 7**, a needle cap **58** is received by the needle opening **56** in an initial pre-use position to shield the injection needle **28**, as shown in **FIG. 8**, prior to use.

[0052] Referring to **FIGS. 10-12**, the activation button **38** includes a body **60** having a top surface **62** for engagement by a user. The top surface **62** of the body **60** extends through the button opening **46** of the housing **12**. A pair of tab members **64** extends outwardly from the body **60** and is received by the top cover **20** of the housing **12**. The body **60** of the activation button **38** includes a lock member **66** extending toward the needle actuator **32**. The activation button **38** is moveable within the housing **12** and is configured to restrict movement of the needle actuator **32**. In particular, when the activation button **38** is in the position shown in **FIG. 10**, the lock member **66** of the activation button **38** will be in interference engagement with the needle actuator **32** to restrict forward movement of the needle actuator **32**. Pressing downward on the activation button **38** will release the lock member **66** from the needle actuator **32** and start the operation of the device **10**, which will be discussed in more detail below.

[0053] Referring to **FIGS. 13-15**, the plunger stop **34** includes a body **70** having an attachment portion **72**, a plunger engagement portion **74**, and an actuator tab **76**. The attachment portion **72** is configured to be rotatably secured to the bottom portion **18** of the housing **12**. The plunger engagement portion **74** extends from the attachment portion **72** and is configured to engage the reservoir **26** as discussed in more detail below. The actuator tab **76** extends from the attachment portion **72** and includes an inclined planar surface **78** that is configured to engage a correspondingly shaped portion of the needle actuator **32**. The plunger stop **34** has a first position, as shown in **FIG. 13**, and a second position, as shown in **FIGS. 14** and **15**.

[0054] Referring to **FIGS. 13** and **16-18**, the reservoir **26** is embodied as a syringe assembly **82** having a syringe barrel **84**, a valve stopper **86**, a plunger **88**, and a fill stopper **90**, although other suitable reservoirs may be utilized. The syringe assembly **82** is configured to be disposed within the housing **12** and arranged along a longitudinal axis of the housing **12**. The syringe barrel **84** defines an interior space **92** for receiving a fluid therein and also receives the valve stopper **86** and fill stopper **90**. The plunger **88** includes a first end **94** and a second end **96** with the second end **96** of the plunger **88** engaged with the valve stopper **86**.

A valve member **98** is received by the valve stopper **86** and is moveable between an open position and a closed position. The valve stopper **86** includes a passageway **102** having an inlet **104** and an outlet **106** generally extending through the valve stopper **86**. The passageway **102** of the valve stopper **86** is in fluid communication with the interior space **92** of the syringe barrel **84** when the valve member **98** is in the open position. A tube (not shown) extends from the outlet **106** of the passageway **102** to the injection needle **28**. The syringe assembly **82** further includes a plunger spring **108** configured to bias the valve stopper **86** towards the fill stopper **90** such that fluid within the syringe barrel **84** is displaced through the passageway **102** of the valve stopper **86**. A plunger guard **110** is disposed over the plunger spring **108**. The first end **94** of the plunger **88** defines a notch **112** configured to engage the plunger engagement portion **74** of the plunger stop **34**. The plunger **88** also includes an elongate arm **114** extending generally parallel to the syringe barrel **84** and configured to engage the needle stop **36** based on a predetermined position of the plunger **88** relative to the syringe barrel **84**. The plunger **88** is configured to move the valve stopper **86** toward the fill stopper **90** to dispense medicament or fluid from the syringe barrel **84**.

[0055] Referring to **FIGS. 6** and **7**, the syringe assembly **82** also includes a fill cover **116** that seals and encloses the fill stopper **90**. The fill cover **116** provides access to the fill stopper **90** during assembly of the device **10**. The fill cover **116** is configured to be secured to the housing **12** without being removable by a user of the device **10**.

[0056] Referring to **FIGS. 19-22**, the needle stop **36** includes a body **120** that defines a central opening **122** for receiving a pin **124** extending upward from the bottom portion **18** of the housing **12**. The body **120** of the needle stop **36** is rotatable about the pin **124** and includes an actuator surface **126** and a plunger surface **128**. The actuator surface **126** and the plunger surface **128** are configured to engage the needle actuator **32** and the plunger **88**, respectively. The plunger surface **128** is raised and positioned upwardly from the actuator surface **126**.

[0057] Referring to **FIGS. 23-29** and **32**, the needle actuator **32** includes an elongate body **132** with a first end **134** and a second end **136**. The body **132** of the needle actuator **32** includes a pair of sidewalls **138** extending between the first and second ends **134**, **136**. The body **132** of the actuator **32** defines an interior space **140** configured to receive a portion of the needle carrier **30**. First and second ramp portions **142**, **144** extend inward from one of the sidewalls **138** toward the interior space **140**. The first ramp portion **142** includes a downward inclined section **146** and a level section **148**. The downward inclined section **146** of the first

ramp portion **142** extends toward the bottom portion **18** of the housing **12** and towards the second end **136** of the needle actuator **32**. The level section **148** is generally parallel to the bottom surface **54** of the bottom portion **18** of the housing **12** and is positioned intermediate the ends **134, 136** of the needle actuator **32**. The second ramp portion **144** includes an upward inclined section **150** extending away from the bottom portion **18** of the housing **12** and towards the second end **136** of the needle actuator **32**. The second ramp portion **144** also includes a level section **151** that is generally parallel to the bottom surface **54** of the bottom portion **18** of the housing **12**. Each of the sidewalls **138** of the needle actuator **32** includes the first and second ramp portions **142, 144**, although only one of the sidewalls **138** may be provided with the ramp portions **142, 144**. The needle actuator **32** also includes a plunger engagement tab **152** and an indicator tab **154**. The plunger engagement tab **152** includes an inclined planar portion **156** that is configured to engage the actuator tab **76** of the plunger stop **34**. The plunger engagement tab **152** is disposed adjacent to the first end **134** of the body **132** of the needle actuator **32**. The indicator tab **154** includes a planar surface **158** having first and second indicator colors **160, 162**. The indicator tab **154** is disposed towards the first end **134** of the body **132** of the needle actuator **32** and is arranged substantially perpendicular to one of the sidewalls **138**.

[0058] Referring to **FIGS. 12, 23-29**, and **32**, the needle actuator **32** further includes a button engagement **164** extending substantially perpendicular to one of the sidewalls **138** and positioned intermediate the first and second ends **134, 136** of the needle actuator **32**. The button engagement **164** is configured to engage the lock member **66** of the activation button **38**. Upon downward movement of the activation button **38**, the button engagement **164** of the needle actuator **32** is configured to be released from engagement with the lock member **66** of the activation button **38**. As shown in **FIG. 12**, a bottom **165** of the needle actuator **32** defines a bottom opening **166**. Further, the needle actuator **32** includes a needle spring **168** disposed within the interior space **140** of the needle actuator **32** and is configured to bias the needle actuator **32** forward toward the first end **14** of the housing **12**. The needle actuator **32** also includes a pad **170** disposed within the interior space **140** of the needle actuator **32** and positioned on a bottom surface **172** of the needle actuator **32**. The pad **170** is constructed from a rubber material, although other suitable materials may be utilized. Thus, the needle actuator **32** has a first position disposed adjacent to the second end **16** of the housing **12** and a second position disposed adjacent to the first end **14** of the housing **12** with the needle spring **168** configured to move the needle actuator **32** from the first position to the second position.

[0059] Referring to **FIGS. 9, 10, and 12**, the needle carrier **30** includes an elongate body **180** having a first end **182** and a second end **184**. The body **180** of the needle carrier **30** includes an attachment member **186** at the first end **182** of the body **180** that is configured to be secured to the bottom portion **18** of the housing **12**. The needle carrier **30** is arranged to be generally cantilevered from the attachment member **186** and extending from the first end **14** of the housing **12** towards the second end **16** of the housing **12**. A portion of the needle carrier **30** is configured to be received by and engaged with the needle actuator **32**. The needle carrier **30** also includes a first engagement **188** disposed between the ends **182, 184** of the body **180** of the needle carrier **30** and a second engagement **190** disposed adjacent the second end **184** of the body **180** of the needle carrier **30**. The first and second engagements **188, 190** extend radially outward from the body **180** and substantially perpendicular to a longitudinal axis of the needle carrier **30**. The needle carrier **30** further includes a generally cylindrical needle receiver **192** that receives and engages the injection needle **28**. The needle carrier **30** defines a passageway **194** having an inlet **196** that is configured to receive the tubing (not shown) from the outlet **106** of the valve stopper **86** of the syringe assembly **82**. A lumen (not shown) of the injection needle **28** is in fluid communication with the passageway **194** and the tubing from the valve stopper **86**. The needle carrier **30** is generally flexible or semi-rigid to allow the needle carrier **30** to flex from a non-biased state and return to the non-biased state after flexing.

[0060] Referring to **FIGS. 9-32**, upon assembly of the device **10**, the device **10** will be in an initial, pre-use state. As discussed in more detail below, the device **10** has a pre-use state, a use state, and a completed state. In the initial state, the syringe assembly **82** is received by the bottom portion **18** of the housing **12** and generally extends from the first end **14** of the housing **12** to the second end **16** of the housing **12**. The medicament is provided within the syringe barrel **84** and the plunger **88** is in a fully retracted position as shown in **FIG. 9**. The plunger spring **108** engages the bottom portion **18** of the housing **12** and the plunger **88** to bias the plunger **88** and valve stopper **86** towards the fill stopper **90**. The valve member **98** arranged within the valve stopper **86** is in a closed position. The attachment portion **72** of the plunger stop **34** is secured to the bottom portion **18** of the housing **12** and allows the plunger stop **34** to rotate relative to the bottom portion **18** of the housing **12**. The plunger engagement portion **74** of the plunger stop **34** engages the notch **112** of the plunger **88** to restrict movement of the plunger **88** towards the fill stopper **90**. The activation button **38** is in a raised position with the top surface **62** of the body **60** extending through the button opening

46 of the housing 12. The lock member 66 is engaged with the button engagement 164 of the needle actuator 32 and prevents movement of the needle actuator 32. The needle actuator 32 is positioned adjacent to the second end 16 of the housing 12 with the second end 136 of the needle actuator 32 abutting the second end 16 of the housing 12. The needle spring 168 is disposed within the interior space 140 of the needle actuator 32 with a first end 200 of the spring 168 engaging the first end 134 of the needle actuator 32 and a second end 198 of the needle spring 168 engaging a spring seat 202 on the bottom portion 18 of the housing 12. Thus, the needle actuator 32 is biased by the needle spring 168 and configured to move the needle actuator 32 from the second end 16 of the housing 12 to the first end 14 of the housing 12 upon release of the button engagement 164 with the lock member 66 of the activation button 38.

[0061] The syringe barrel 84 may be filled with a medicament by any suitable method. In one embodiment, with the fill cover 116 and fill stopper 90 removed from the housing 12, the syringe barrel 84 is filled with medicament. A guide tube (not shown), which has a slightly smaller diameter than the inner diameter of the syringe barrel 84, is used to squeeze and place the fill stopper 90 just above the medicament before retracting and leaving the fill stopper 90 in place. A further method uses a machine or apparatus to engage the top of the syringe barrel 84 and evacuate the syringe barrel 84 to a preset vacuum. When the preset vacuum is reached, the fill stopper 90 is pushed down into the syringe barrel 84 and the vacuum is released which causes atmospheric pressure to draw the fill stopper 90 into place while leaving no air gap. Another method of filling the syringe barrel 84 utilizes a piece of wire or string along the outside of the fill stopper 90 while the fill stopper 90 is positioned within the syringe barrel 84. The wire or string creates a temporary break in the seal that allows air to escape from between the fill stopper 90 and the medicament as the fill stopper 90 is pushed into place.

[0062] In the initial, pre-use state of the device 10, the needle carrier 30 has a non-biased position with the elongate body 180 of the needle carrier 30 being substantially planar. The attachment member 186 of the needle carrier 30 is rotatably secured to a carrier seat 204 extending upwardly from the bottom portion 18 of the housing 12. A portion of the needle carrier 30 is disposed within the needle actuator 32 with the elongate body 180 of the needle carrier 30 extending substantially parallel to the needle actuator 32. The first engagement 188 of the needle carrier 30 is positioned adjacent to the first ramp portion 142 of the needle actuator 32. The plunger engagement tab 152 of the needle actuator 32 is positioned adjacent

to the actuator tab **76** of the plunger stop **34**. Further, the indicator tab **154** of the needle actuator **32** is positioned such that the first indicator color **160** is visible through the first indicator lens **48** of the housing **12** to indicate that the device **10** is ready to use.

[0063] Referring to **FIGS. 14** and **15**, after removing the needle cap **58** from the needle opening **56** in the bottom portion **18** of the housing **12** and depressing the activation button **38** to move the activation button **38** further within the housing **12**, the device **10** transitions from the pre-use position to the use position. After pressing the activation button **38**, the lock member **66** of the activation button **38** is released from the button engagement **164** of the needle actuator **32** to allow forward movement of the needle actuator **32** towards the first end **14** of the housing **12**. The needle actuator **32** moves forward, as shown in **FIG. 14**, and the plunger engagement tab **152** of the needle actuator **32** engages the actuator tab **76** of the plunger stop **34** thereby causing the plunger stop **34** to rotate downward to the position shown in **FIG. 15**. After the plunger stop **34** has rotated downward a sufficient distance, the plunger engagement portion **74** of the plunger stop **34** is released from the notch **112** of the plunger **88** thereby allowing the plunger **88** to be moved toward the fill stopper **90** by the plunger spring **108**. Upon movement of the plunger **88**, the valve member **98** within the valve stopper **86** is moved to the open position to place the injection needle **28** in fluid communication with the syringe barrel **84**. In particular, in the pre-use position, the plunger **88** is moveable within the valve stopper **86** a predetermined distance. When the plunger **88** disengages from the plunger stop **34**, the plunger **88** moves within the valve stopper **86** and causes the valve member **98** to move to the open position. Movement of the valve stopper **86** toward the fill stopper **90** causes fluid within the syringe barrel **84** to move through the passageway **102** in the valve stopper **86** through the tubing (not shown) and through the lumen of the injection needle **28**.

[0064] Referring to **FIGS. 23** and **24**, when the device **10** is transitioned to the use state from the pre-use state, the injection needle **28** is moved to a use position where the injection needle **28** extends through the needle opening **56** in the bottom portion **18** of the housing **12**. In use, the bottom surface **54** of the bottom portion **18** of the housing **12** will be arranged against a target surface of a patient's body such that the injection needle **28** pierces the target surface of the patient. As discussed above, when the injection needle **28** is moved from the initial position to the use position, fluid within the syringe barrel **84** is automatically supplied to the lumen of the injection needle **28** for infusion into the patient.

[0065] Referring to **FIGS. 29** and **30**, during the transition of the injection needle **28** from the initial position to the use position, the needle carrier **30** is pre-loaded to snap the needle carrier **30** downward to quickly pierce the target area of a patient's body with the injection needle **28**. In particular, as the needle actuator **32** moves forward toward the first end **14** of the housing **12**, the first engagement **188** of the needle carrier **30** engages the bottom of the inclined section **146** of the first ramp portion **142** while the second engagement **190** of the needle carrier **30** engages the top of the level section **148** of the first ramp portion **142**. Further movement of the needle actuator **32** causes the intermediate portion between the first and second ends **182**, **184** of the needle carrier **30** to flex, as shown in **FIG. 30**, while the second end **184** of the needle carrier **30** is supported by the level section **148** of the first ramp portion **142**. Continued movement of the needle actuator **32** causes the second engagement **190** of the needle carrier **30** to extend beyond the level section **148** of the first ramp portion **142** thereby releasing the second end **184** of the needle carrier **30** and causing the needle carrier **30** and injection needle **28** to snap downwardly.

[0066] Referring to **FIG. 23**, when the device **10** is in the use state and the injection needle **28** is in the use position, the needle carrier **30** is positioned between the first and second ends **14**, **16** of the housing **12**. The first indicator color **160** of the indicator tab **154** is positioned below the second indicator lens **50** of the housing **12** to indicate that the device **10** is in the use state.

[0067] Referring to **FIGS. 19** and **20**, continued movement of the needle actuator **32** is restricted when the device **10** is in the use state until a predetermined amount of medicament has been dispensed from the syringe barrel **84**. In particular, the actuator surface **126** of the needle stop **36** engages the needle actuator **32** and the plunger surface **128** engages the elongate arm **114** of the plunger **88**. The needle stop **36** is restricted from rotating when the needle actuator **32** engages the needle stop **36** due to the interference of the plunger surface **128** of the needle stop **36** with the elongate arm **114** of the plunger **88**. Upon further movement of the plunger **88**, such as when the valve stopper **86** engages the fill stopper **90**, the plunger surface **128** of the needle stop **36** will be free from interference with the elongate arm **114** of the plunger **88** to allow the needle actuator **32** to rotate the needle stop **36** and continue movement of the needle actuator **32** toward the first end **14** of the housing **12**.

[0068] Referring to **FIGS. 21**, **22**, and **25-28**, as the needle actuator **32** is moved past the needle stop **36** toward the first end **14** of the housing **12**, the device **10** is transitioned from the use state to the completed state. As discussed above, after the plunger **88** moves the valve

stopper **86** into engagement with the fill stopper **90** after a predetermined amount of time, the needle stop **36** rotates and allows the needle actuator **32** to move to the first end **14** of the housing **12** with the first end **134** of the needle actuator **32** abutting the first end **14** of the housing **12**, as shown in **FIG. 26**. The rotation of the needle stop **36** and the clearing of the elongate arm **114** of the plunger **88** is shown in **FIGS. 21** and **22**. The injection needle **28** is transitioned from the use position to the shielded position where the lumen of the injection needle **28** is blocked and where the injection needle **28** is positioned within the housing **12**. In particular, in the shielded position, the injection needle **28** engages the pad **170** positioned within the needle actuator **32** to block the lumen of the injection needle **28** and prevent fluid from exiting the injection needle **28**. In the completed state of the device, the second indicator color **162** of the indicator tab **154** of the needle actuator **32** is positioned below the third indicator lens **52** of the housing **12** to indicate the completed state of the device **10**. Further, as shown in **FIG. 28**, the bottom **165** of the needle actuator **32** closes the needle opening **56** in the bottom portion **18** of the housing **12**.

[0069] Referring to **FIGS. 25, 29**, and **31**, during the transition of the injection needle **28** from the use position to the shielded position, the needle carrier **30** is pre-loaded to snap the needle carrier **30** downward to engage the pad **170** positioned within the needle actuator **32**. As the needle actuator **32** moves forward toward the first end **14** of the housing **12**, the first engagement **188** of the needle carrier **30** engages the bottom of the level section **148** of the first ramp portion **142** while the second engagement **190** of the needle carrier **30** engages the top of the inclined section **150** of the second ramp portion **144**. Further movement of the needle actuator **32** causes the second end **184** of the needle carrier **30** to flex upwardly as the second engagement **190** proceeds along the inclined section **150** of the second ramp portion **144** while the first engagement **188** slides along the level section **148** of the first ramp portion **142**. Continued movement of the needle actuator **32** towards the first end **14** of the housing **12** causes the second engagement **190** of the needle carrier **30** to extend beyond the level section **151** of the second ramp portion **144** thereby causing the needle carrier **30** and injection needle **28** to snap downwardly into the pad **170**. After the injection needle **28** engages the pad **170**, the lumen of the injection needle **28** is blocked by the pad **170** to prevent fluid from leaking out of the device **10** when the device **10** is in the completed state.

[0070] Referring to **FIGS. 33-36**, a second embodiment of a device **220** for delivering a fluid into a patient by injection is shown. The device **220** is similar to the device **10** shown in **FIGS. 1-32**, expect for the differences discussed below. Like reference numbers are used for

like elements. Instead of providing the first, second, and third indicator lenses **48, 50, 52,** the device **220** shown in **FIGS. 33-36** includes an indicator lens **222** that extends outward from the top cover **20** of the housing **12**. Further, the needle actuator **32** includes a raised indicator tab **224** that extends upwardly from the body **132** of the needle actuator **32**. The raised indicator tab **224** of the needle actuator **32** extends into the indicator lens **222** and is received by the indicator lens **222**. The needle actuator **32** also includes an indicator post **226** that extends outward from the first end **134** of the needle actuator **32**. The first end **14** of the housing **12** defines an indicator opening **228** configured to receive the indicator post **226**. As the device **220** is moved from the pre-use state, the use state, and the completed state, the indicator tab **224** on the needle actuator **32** will move within the indicator lens **222** to provide an indication of the state of the device **220**. Further, when the device **220** is in the completed state, the indicator post **226** of the needle actuator **32** will protrude through the indicator opening **228** of the housing **12** to provide visual and tactile feedback of the completed state of the device **220**. The indicator tab **224** and the indicator lens **222** arrangement of the present embodiment allows the indicator tab **224** to be viewed from a larger viewing area compared to the indicator arrangement of the first embodiment.

[0071] Referring again to **FIGS. 33-36**, the device **220** of the second embodiment also includes a two piece activation button **230** having a first portion **232** and a second portion **234**. The first portion **232** is moveable relative to the second portion **234** and has a locked position (shown in **FIG. 34**) and a use position (shown in **FIG. 33**). When the first portion **232** is in the locked position, a protrusion **236** extends radially outward to interfere with the button opening **46** in the top cover **20** of the housing **12** to prevent the activation button **38** from being depressed. When the first portion **232** of the activation button **230** is moved to the use position, the protrusion **236** is received by the second portion **234** and allows the activation button **230** to be depressed to begin the injection process. The activation button **230**, however, otherwise operates in a similar manner as described above in connection with the first embodiment. Accordingly, the two-piece activation button **230** allows the activation button to be locked to prevent accidental operation of the device.

[0072] While several embodiments were described in the foregoing detailed description, those skilled in the art may make modifications and alterations to these embodiments without departing from the scope and spirit of the invention. Accordingly, the foregoing description is intended to be illustrative rather than restrictive. The invention described hereinabove is

defined by the appended claims and all changes to the invention that fall within the meaning and the range of equivalency of the claims are embraced within their scope.

WHAT IS CLAIMED IS:

1. A device for delivering a fluid comprising:

a housing defining an interior space and having a bottom surface configured for contacting a patient, the bottom surface defining a needle opening;

a reservoir disposed within the interior space of the housing for containing a fluid therein;

a needle carrier disposed within the housing;

an injection needle supported by the needle carrier and defining a lumen, the lumen of the injection needle configured to be placed in fluid communication with the reservoir, wherein the injection needle is transitionable from an initial position in which the injection needle is disposed within the housing, to a use position in which the injection needle extends through the needle opening, and a substantially shielded position in which the injection needle is disposed within the housing;

a needle actuator controlling positioning of the needle carrier and the injection needle; and

an indicator for separately indicating when the injection needle is in the initial position, the use position, and the shielded position;

wherein the indicator comprises an indicator tab disposed on and movable with the needle actuator and the needle actuator closes the needle opening when the injection needle is in the shielded position.

2. The device of claim 1, wherein the housing includes at least one indicator lens, and wherein the indicator is visible from an exterior of the housing via the indicator lens.

3. The device of claim 1, wherein the indicator provides a visual and tactile indication of the position of the injection needle.

4. The device of claim 3, wherein the indicator comprises an indicator post disposed on the needle actuator, and the housing defines an indicator opening, the indicator post being disposed within the housing when the injection needle is in the initial

position and the use position, the indicator post extending through the indicator opening when the injection needle is in the shielded position.

5. The device of claim 1, wherein the indicator comprises at least one indicator lens permitting visual inspection of the needle actuator to separately indicate when the injection needle is in the initial position, the use position, and the shielded position.

6. The device of claim 5, wherein the indicator comprises first through third indicator lenses, each permitting visual inspection of the needle actuator, and respectively indicating when the injection needle is in the initial position, the use position, and the shielded position.