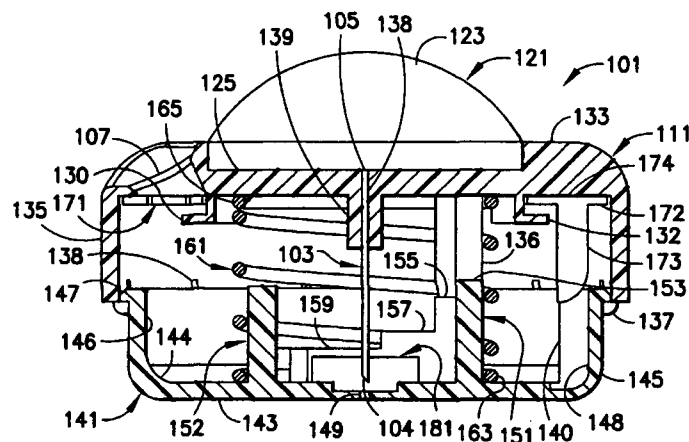


ORIGINAL

**SELF-INJECTION DEVICE**

**ABSTRACT**

A self-injection device (101) for delivering a medicament includes a housing (111), and a needle (103) connected to the housing (111). A compressible reservoir (121) is connected to the housing (111) and is in fluid communication with a needle (103) such that compressing the reservoir (121) delivers medicament from the reservoir (121) to the needle (103) and moves the needle (103) from the first position to the second position. A platform (171) is disposed within the housing (111) about which the housing (111) is rotatable between a plurality of positions. Each of the positions corresponds to a different distance the needle (103) is moved to the second position during an injection to provide a variable injection depth. The needle (103) is withdrawn into the housing (111) after an injection without requiring manual manipulation by the user, thereby preventing needle sticks and other accidents.



**FIG.4**

We claim:

1. A self-injection device for delivering a medicament, comprising:
  - a housing having a first housing part and a second housing part engaged with selectively movable with respect to each other;
  - one of said first and second housing parts having a needle movable between a first position in which a proximal end of the needle is disposed within said housing and a second position in which the proximal end of said needle is disposed outside of said housing; and
  - a compressible reservoir in fluid communication with said needle, compression of said reservoir causing said needle to move from said first position to said second position.
2. The self-injection device of claim 1, wherein said first housing part and said second housing part are rotatable with respect to each other between a plurality of positions, each of said positions setting a distance for movement of said needle between said first and second positions.
3. The self-injection device of claim 2, wherein said plurality of positions define a plurality of depths to which a proximal end of said needle travels in a patient's skin, each of said plurality of said depths corresponding to one of intradermal, junctional or subcutaneous injections.

4. The self-injection device of claim 1, further comprising an elastic septum disposed in an aperture defined in said second housing part, at least a portion of said needle being disposed in said septum.

5. The self-injection device of claim 4, further comprising an adhesive on one of said first and second housing parts to secure said device to a patient's skin during injection.

6. The self-injection device of claim 1, further comprising biasing means normally biasing said first and second housing parts away from each other.

7. The self-injection device of claim 3, wherein said plurality of positions is defined by a tab defined on one of said first and second housing parts, and by a step defined on the other one of said first and second housing parts.

8. The self-injection device of claim 7, wherein said tab and said step comprise at least four steps, a first step preventing movement of said first and second housing parts with respect to each other when said reservoir is compressed, a second step limiting movement of said needle to a first position corresponding to an intradermal injection, a third step limiting movement of said needle to a second position corresponding to a junctional injection, and a fourth step limiting movement of said needle to a third position corresponding to a subcutaneous injection.

9. A self-injection device for delivering a medicament, comprising:

a housing having a first housing part and a second housing part engaged with selectively movable with respect to each other;

one of said first and second housing parts having a needle movable between a position in which the needle is disposed entirely within said housing and a second position in which a proximal end of said needle is disposed outside of said housing;

a compressible reservoir in fluid communication with said needle, compression of said reservoir causing said needle to move from said first position to said second position and

said first housing part and said second housing part being rotatable with respect to each other between a plurality of positions, each of said positions setting a distance of movement of said needle between said first and second positions.

10. The self-injection device according to claim 9, wherein said plurality of positions defines a plurality of depths to which said proximal end of said needle travels through a patient's skin, each of said plurality of positions corresponding to injection depths for intradermal, junctional and subcutaneous injections.

11. The self-injection device of claim 10, further comprising a biasing member between said first and second housing parts, said biasing means normally biasing said first and second housing parts away from each other.

12. The self-injection device of claim 9, wherein said plurality of positions defined by a tab on one of said first and second housing parts, and by a step on the other of said first and second housing parts.

13. The self-injection device of claim 12, wherein said tab and said step comprise at least four steps, a first step preventing movement of said first and second housing parts with respect to each other when said reservoir is compressed, a second step limiting movement of said needle to a first position corresponding to an intradermal injection, a third step limiting movement of said needle to a second position corresponding to a junctional injection, and a fourth step limiting movement of said needle to a third position corresponding to a subcutaneous injection.

14. The self-injection device of claim 9, further comprising an elastic septum disposed in an aperture defined in said second housing part, at least a portion of said needle being disposed in said septum.

15. A method of administering a medicament with an injection device, comprising the steps of:

placing the device on the site where the medicament is to be delivered; and

depressing a reservoir connected to a housing, thereby moving a needle connected to the housing from a first position within the housing to a second position to inject

needle into the site and to cause the medicament contained within the reservoir from reservoir, through the needle and into the site.

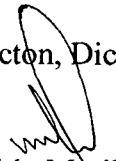
16. The method of claim 15, further comprising the step of selecting a desired injection depth by rotating a first housing part of the housing relative to a second housing part.

17. The method of claim 15, further comprising the step of filling the reservoir prior to delivering the medicament by disposing the device on a medicament container depressing the reservoir to withdraw the medicament from the container and into reservoir.

18. The method of claim 15, further comprising the step of releasing the reservoir to passively withdraw the needle such that a proximal end of the needle is disposed within housing upon releasing the reservoir without manual manipulation of the needle, thereby preventing an accidental needle stick.

Dated this 20<sup>th</sup> day of March, 2012.

Becton, Dickinson and Company

  
(Nitin Masilamani)  
of Amarchand & Mangaldas &  
Suresh A. Shroff & Co.  
Attorneys for the Applicant

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**TOTAL NO. OF SHEETS: 6**  
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**SHEET 1**

20 MAR 2012  
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**(NITIN MASILAMANI)  
OF AMARCHAND & MANGALDAS &  
SURESH A. SHROFF & CO.  
ATTORNEYS FOR THE APPLICANT**

20 MAR 2012  
24 14 DEL 12

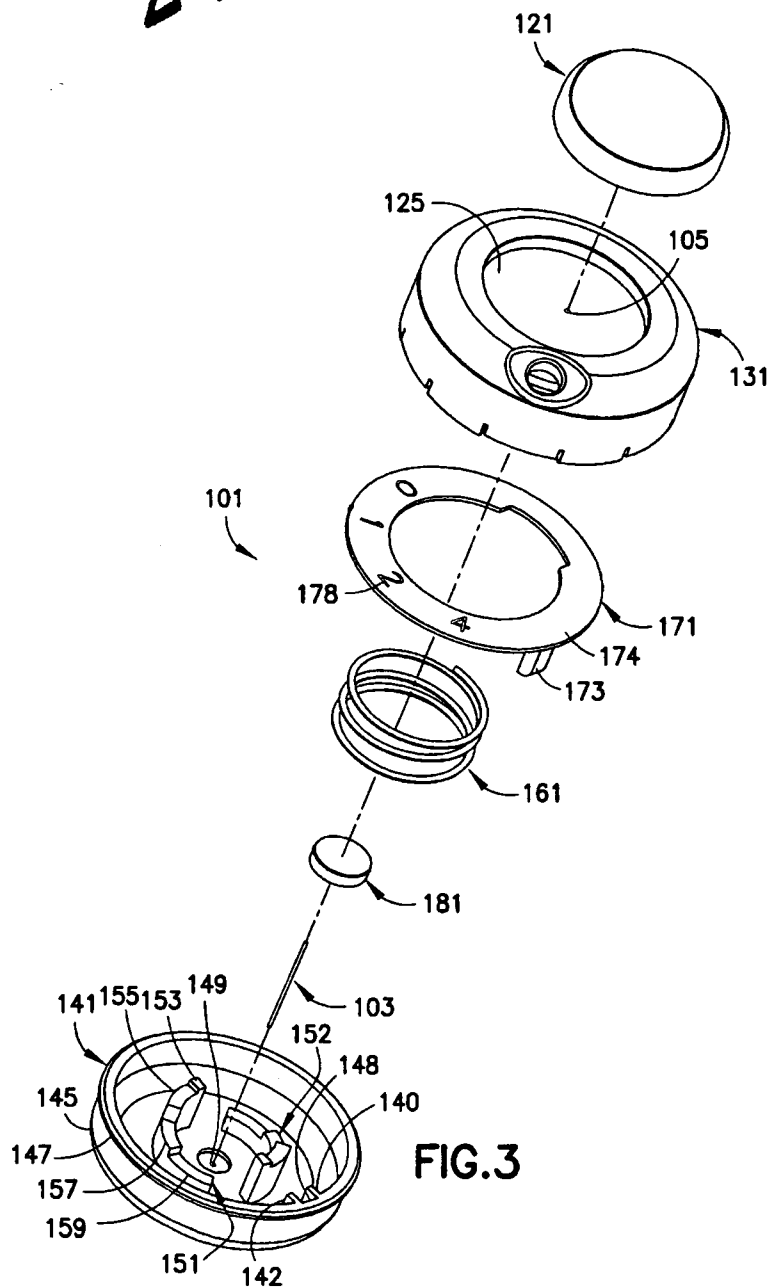


FIG. 3

(NITIN MASILAMANI)  
OF AMARCHAND & MANGALDAS &  
SURESH A. SHROFF & CO.  
ATTORNEYS FOR THE APPLICANT



20 MAR 2012  
2414 DEN 12



**(NITIN MASILAMANI)  
OF AMARCHAND & MANGALDAS &  
SURESH A. SHROFF & CO.  
ATTORNEYS FOR THE APPLICANT**

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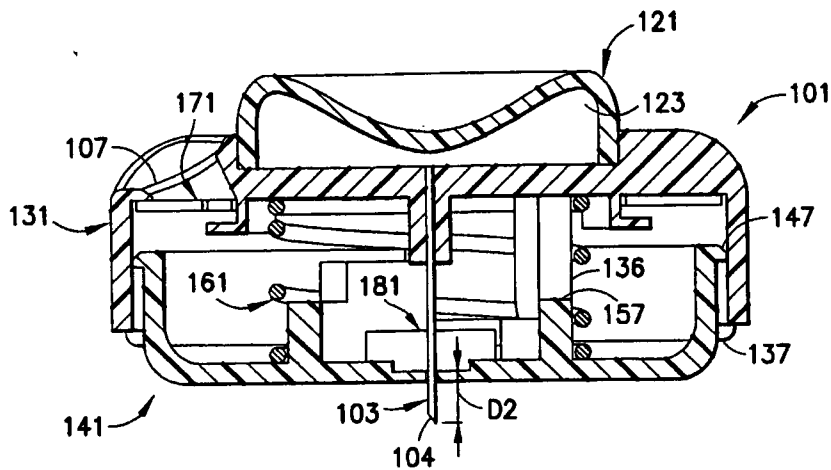


FIG. 6

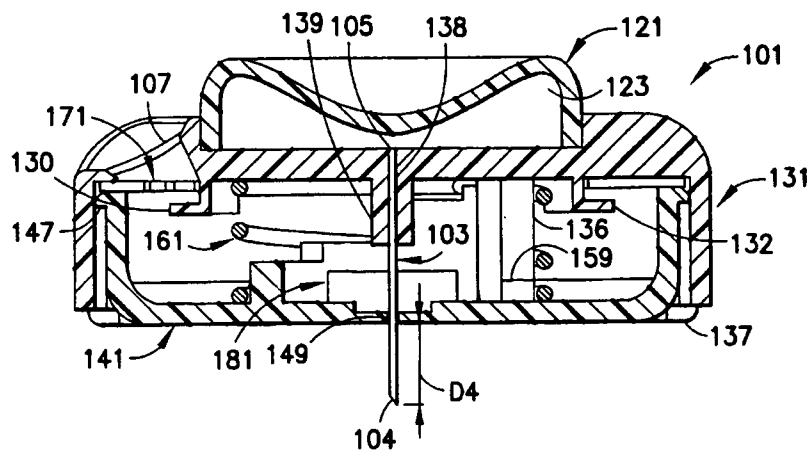


FIG. 7

*(Signature)*  
(NITIN MASILAMANI)  
OF AMARCHAND & MANGALDAS &  
SURESH A. SHROFF & CO.  
ATTORNEYS FOR THE APPLICANT

20 MAR 2012  
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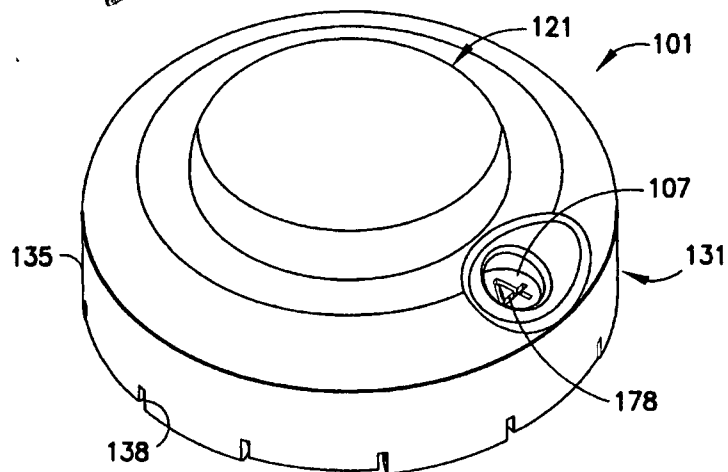


FIG. 8

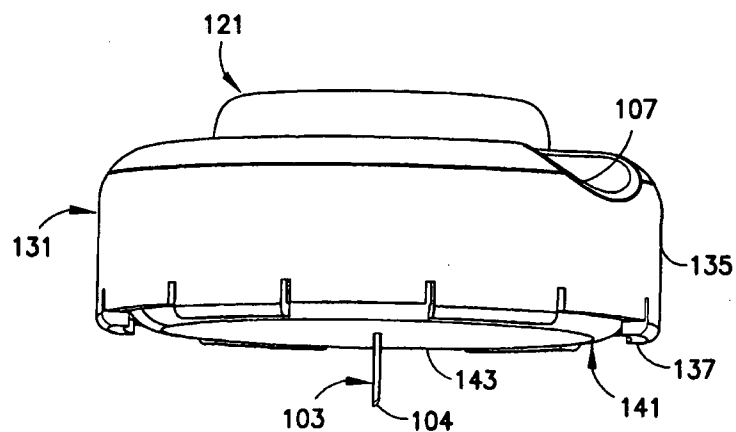

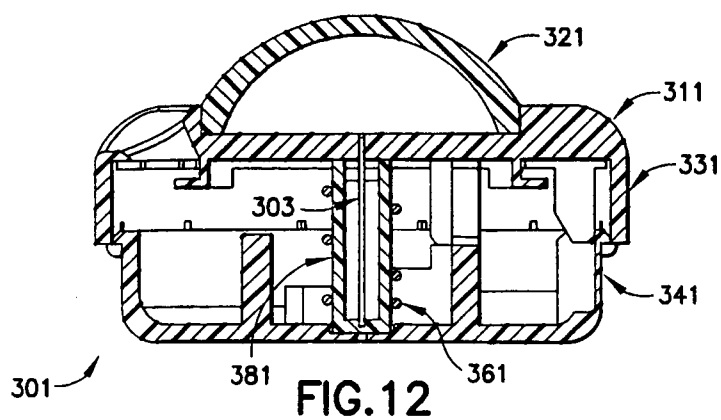
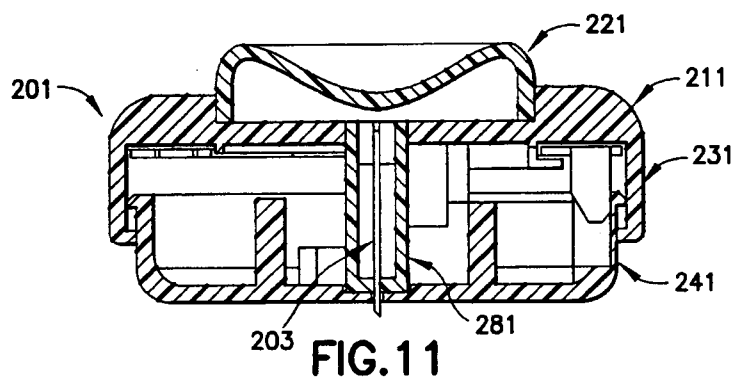
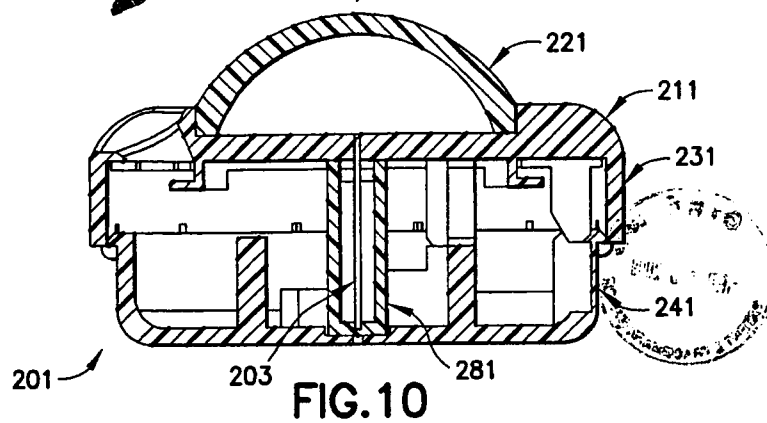


FIG. 9

  
(NITIN MASILAMANI)  
OF AMARCHAND & MANGALDAS &  
SURESH A. SHROFF & CO.  
ATTORNEYS FOR THE APPLICANT

20 MAR 2012  
2414 DELNP 12



(NITIN MASILAMANI)  
OF AMARCHAND & MANGALDAS &  
SURESH A. SHROFF & CO.  
ATTORNEYS FOR THE APPLICANT

## **SELF-INJECTION DEVICE**

### **Field of the Invention**

[0001] The present invention relates to a self-injection device. More particularly, present invention relates to a self-injection device having a compressible reservoir. Still more particularly, the present invention relates to a self-injection device having an adjustable injection depth to allow an intradermal, junctional or subcutaneous injection, as well as allowing the self-injection device to be filled with a medicament. Still more particularly, the self-injection device has a passive safety mechanism to prevent accidental needle sticks.

### **Background of the Invention**

[0002] Syringes are used to inject medicaments into tissue areas, such as the subcutaneous tissue layer, the intradermal tissue layer or the junctional area between the intradermal and subcutaneous tissue layers. However, existing syringes are only able to deliver medicament to one of these tissue layers. Thus, a separate inventory of syringes is required for delivering medicament to each of the intradermal, junctional and subcutaneous tissue layers, thereby increasing inventory and manufacturing costs.

[0003] Accordingly, a need exists for a syringe adapted to deliver medicament to any of the intradermal, subcutaneous and junctional tissue layers.

[0004] Additionally, a need exists for incorporation of safety mechanisms into such a device to prevent the spread of bacterial and viral pathogens via a needle stick or other accident.

### Summary of the Invention

[0005] The self-injection device according to an exemplary embodiment of the present invention has an adjustable injection depth, thereby allowing intradermal, junctional subcutaneous injections with the same self-injection device.

[0006] In accordance with an exemplary embodiment of the present invention, a self-injection device includes a housing, and a needle connected to the housing. The needle is movable between a first position in which a proximal end of the needle is disposed within the housing and a second position in which the proximal end of the needle is disposed outside the housing. A compressible reservoir is connected to the housing and in fluid communication with the needle such that compressing the reservoir delivers medication from the reservoir to the needle and moves the needle from the first position to the second position.

[0007] In accordance with another exemplary embodiment of the present invention, a self-injection device includes a housing, and a needle connected to the housing. The needle is movable between a first position in which the needle is disposed entirely within the housing and a second position in which a proximal end of the needle is disposed outside the housing. A platform is disposed within the housing about which the housing is rotatable between a plurality of positions. Each of the positions corresponds to a different distance the needle is moved to the second position during an injection.

[0008] In accordance with another exemplary embodiment of the present invention, a method of administering a medicament with an injection device is provided. The device is placed on the site where the medicament is to be delivered. A reservoir, which is connected

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to the housing and to a needle disposed in the housing, is depressed to inject the needle the site and to deliver the medicament stored in the reservoir from the reservoir, through needle and into the site. The desired injection depth is selected by rotating an upper housing of the housing relative to a lower housing.

### **Brief Description of the Drawings**

[0009] The above benefits and other advantages of the various embodiments of present invention will be more apparent from the following detailed description of exemplary embodiments of the present invention and from the accompanying drawing figures, in which

[0010] FIG. 1 is a perspective view of a self-injection device according to an exemplary embodiment of the present invention;

[0011] FIG. 2 is an elevational view of the self-injection device of FIG. 1;

[0012] FIG. 3 is an exploded perspective view of the self-injection device of FIG. 1;

[0013] FIG. 4 is an elevational view in partial cross-section of the self-injection device of FIG. 1;

[0014] FIG. 5 is an elevational view in cross-section of the self-injection device set for intradermal injection;

[0015] FIG. 6 is an elevational view in cross-section of the self-injection device set for intramuscular injection;

[0016] FIG. 7 is an elevational view in cross-section of the self-injection device set for subcutaneous injection;

[0017] FIG. 8 is a perspective view from above of the self-injection device of FIG. 7;

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[0018] FIG. 9 is a perspective view from below of the self-injection device of FIG. 8;

[0019] FIG. 10 is an elevational view in partial cross-section of another exemplary embodiment of a self-injection device having an elongated septum;

[0020] FIG. 11 is an elevational view in partial cross-section of the self-injection device of FIG. 10 in which the reservoir is depressed; and

[0021] FIG. 12 is an elevational view in partial cross-section of another exemplary embodiment of a self-injection device having an elongated septum and a spring.

[0022] Throughout the drawings, like reference numbers will be understood to refer to like parts, components and structures.

#### **Detailed Description of the Exemplary Embodiment**

[0023] A self-injection device 101 according to an exemplary embodiment of the present invention, as shown in FIGS. 1 – 9, includes a housing 111, a needle 103 connected to the housing, and a compressible reservoir 121 connected to the housing. The needle 103 is movable between a first position as shown in FIG. 4, in which the proximal end 104 of the needle is disposed within the housing 111, and a second position in which a proximal end 104 of the needle is disposed outside of the housing as shown in FIGS. 5 – 7. The reservoir 121 is in fluid communication with the needle 103 such that compressing the reservoir delivers medicament from the reservoir to the needle and moves the needle from the first position to the second position.

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[0024] The housing 111 includes an upper housing 131 and a lower housing 141 shown in FIGS. 3 – 4. The housing is made of a suitable plastic material, such polypropylene.

[0025] The upper housing 131 has a base 133 and a wall 135 extending substantially perpendicularly from an outer edge thereof. A free end of the wall 135 has a plurality inwardly extending tabs 137. Cut-out portions 138 are formed in the wall 135 adjacent tabs 137 to facilitate the flexibility of the tabs. A projection 139 extends outwardly from inner surface 134 of the base 133 of the upper housing 131. An opening 138 extends through the entire length of the projection 139. A first tab (not shown) and a second tab 136 extend downwardly from the inner surface 134 and are diametrically opposed with respect to projection 139. First and second flanges 130 and 132 extend downwardly from the inner surface 134 and are diametrically opposed with respect to the projection 139. Preferably, first and second flanges 130 and 132 are substantially L-shaped and are disposed radially outwardly of the first and second tabs 136 and 138 relative to the projection 139. A window 107 is formed in the base 133 of the upper housing 131. The upper housing preferably has an outer diameter of approximately 31 millimeters.

[0026] The lower housing 141 has a base 143 and a wall 145 extending substantially perpendicularly from an outer edge thereof, as shown in FIGS. 2 and 4. A free end of wall 145 has an outwardly extending lip 147. An opening 149 in the base 143 is adapted to allow a needle 103 to pass therethrough. A groove 148 is formed on an inner surface 144 of the wall 145, as shown in FIG. 3. The groove 148 is formed between first and second members 140 and 142. The distance from the outer surface of the base 143 of the lower housing 141 to the inner surface 144 of the wall 145 is approximately 1.5 millimeters.

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housing 141 to the outer surface of the base 133 of the upper housing 131 is preferably approximately 15 millimeters. The distance from the outer surface of the base 143 of lower housing 141 to the top of the uncompressed reservoir 121 is preferably approximately 21 millimeters.

[0027] An adhesive backing may be disposed on the outer surface of the base 143 of lower housing 141 to substantially prevent movement of the self-injection device 101 when placed on a skin surface to perform an injection. The adhesive backing may also assist in immobilizing, fixing, stretching or spreading the skin to facilitate the injection.

[0028] A series 151 of steps 153, 155, 157 and 159 extend upwardly from an inner surface 144 of the base 143, as shown in FIG. 3. Preferably, there are four adjacent steps of decreasing height. The first step 153 is the highest step and is adapted to prevent downward movement of the top housing 131 and the needle 103. The second step 155 is adjacent the first step 153 and is adapted to allow movement of the needle 104 for an intradermal injection. The third step 157 is adjacent the second step 155 and is adapted to allow movement of the needle for a junctional injection. The fourth step 159 is adjacent the third step 157 and is adapted to allow movement of the needle for a subcutaneous injection. Preferably, a second set of identical steps are diametrically opposed from the first series of steps 151 with regard to the opening 149 in the base 145. Although this exemplary embodiment provides three different injection depths, the present invention is not limited to such embodiment and fewer or more injection depths are within the scope of the invention.

[0029] The skin is made up of three layers: epidermis, dermis and subcutaneous layer. The epidermis is the outermost layer of the skin, with the dermis layer underlying

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epidermis, and the subcutaneous layer underlying the dermis. An intradermal injection is made in the dermis layer, and requires an injection depth of approximately 1 mm. A junctional injection is made in the junction between the dermis and the subcutaneous layer and requires an injection depth of approximately 2 mm. A subcutaneous injection is made in the subcutaneous layer, and requires an injection depth of approximately 4 mm.

[0030] A spring 161 is disposed inside the housing 111, as shown in FIGS. 3 and 4. A first end 163 of the spring 161 abuts the inner surface 144 of the base 143 of the lower housing 141. A second end 165 of the spring 161 abuts the inner surface 134 of the base 133 of the upper housing 131. Preferably, the spring 161 is disposed radially outwardly of the steps 153, 155, 157 and 159 of the lower housing 141 and the tabs 136 of the upper housing 131, as shown in FIG. 4.

[0031] A platform 171 is disposed adjacent the inner surface 134 of the base 133 of the upper housing and is secured thereto by the first and second flanges 130 and 132, as shown in FIGS. 3 and 4. A stop 173 extends outwardly from a lower surface 172 of the platform 171. The stop 173 is received by the groove 148 formed on an inner surface of the wall 145 of the lower housing 141. The stop 173 is received in the groove 148, thereby allowing the upper housing 131 to rotate relative to the platform 171, which is prevented from rotating by the stop 173 disposed in the groove 148 of the lower housing 141. A plurality of position indicators 178 are marked on an upper surface 174 of the platform 171 and are visible through the window 107 in the upper housing 131, as shown in FIGS. 3 and 8.

[0032] A compressible reservoir 121 is connected to the upper housing 131, as shown in FIGS. 1 – 3. A volume 123 is formed within the reservoir 121 defined by the reservoir

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and the upper housing 131 in which medicament is stored. A recess 125 is formed in upper surface 133 of the upper housing 131 to receive the compressible reservoir 121. The compressible reservoir 121 may be secured to the upper housing 131 in any suitable manner such as by providing an outwardly extending flange on the compressible reservoir 121 that is received within a groove formed in the recess 125, by an adhesive that secures the compressible reservoir 121 in the recess 125, or by an interference fit between the compressible reservoir 121 and the recess 125. The compressible reservoir 121 is made of a suitable flexible plastic or elastomeric material, such as vylon or silicone rubber.

[0033] The needle 103 is fixedly connected to the base 133 of the upper housing 131 shown in FIGS. 4 – 7. The needle 103 has a distal end 105 flush with the opening 138 in the recess 125 of the upper housing 131. The proximal end 104 of the needle 103 is disposed within the housing 111 when the upper housing 131 is in its initial position, as shown in FIG. 4. Preferably, the proximal end 104 of the needle 103 is disposed within a resilient septum 181 when the upper housing 131 is in its initial position.

[0034] The septum 181 is connected to an inner surface 144 of the base 143 of the lower housing 141, as shown in FIG. 4, and covers the opening 149 in the lower housing. The septum 181 is preferably solid and elastic, and allows the needle 103 to pass therethrough when the needle is moved during an injection. The septum 181 acts as a shield and seal covering the proximal end 104 of the needle 103, thereby preventing accidental needle stick and sealing the opening 149. The septum is made of an appropriate elastomeric material such as silicone rubber.

[0035] The self-injection device 101 may be pre-filled or filled by the user. The procedure for filling the self-injection device 101 with medicament is substantially similar to the procedure for injecting medicament into a site, and is described hereafter.

[0036] The self-injection device is shown in the locked position in FIG. 4. The tabs 153 prevent the upper housing 131 from moving about the first step 153, thereby preventing downward movement of the upper housing 131 relative to the lower housing 141. The proximal end 104 of the needle 103 is disposed within the housing 111, and preferably within the septum 181. An indicator on the platform 171 is visible through the window 107 of the upper housing 131 to indicate that the self-injection device 101 is in the locked position, such as the numeral "0" (FIG. 3) to indicate that the needle 103 is movable 0 millimeters in this setting, i.e., not movable.

[0037] The inner diameter of the upper housing 131 is larger than the outer diameter of the lower housing 141, as shown in FIG. 4. Thus, the upper housing 131 is movable downwardly over the lower housing 141, as shown in FIGS. 5 – 9. The tabs 137 of the upper housing 131 prevent the upper housing from being separated from the lower housing 141 by engaging the outwardly extending lip 147 when the spring 161 expands after an injection. The slots 138 in the upper housing provide flexibility to the tabs 137 such that the tabs 137 may be flexed over the lip 147 during initial assembly of the self-injection device 101.

[0038] The self-injection device is shown in a position corresponding to an intradermal injection in FIG. 5. The upper housing 131 is rotated relative to the platform 171 such that the indicator visible through the window 107 indicates that the self-injection device 101 is in an intradermal position. The indicator may be the numeral "1" (FIG. 3) to indicate that the needle 103 is movable one millimeter, which corresponds to the depth required for

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intra dermal injection. The stop 173 of the platform 171 is disposed within the groove 148 of the lower housing 141, thereby preventing rotation of the platform 171 and lower housing 141 when the upper housing 131 is rotated. To perform the intra dermal injection, the reservoir 121 is depressed, thereby moving the upper housing 131 downwardly until the tabs 154 abut the second step 155. The spring 161 is compressed between the upper and lower housings 131 and 141, respectively. This results in approximately one millimeter of travel for the needle 103 beyond the base 143 of the lower housing 141, as shown by the distance D1 of FIG. 5. Preferably, the distance from the outer surface of the base 143 of the lower housing 141 to the outer surface of the base 133 of the upper housing 131 when the reservoir 121 is compressed for an intra dermal injection is preferably approximately 13 millimeters.

[0039] The needle 103 is fixed to and moves with the upper housing 131. The proximal end 104 of the needle 103 passes through the septum 181 and through the opening 149 in the base 143 of the lower housing 141. Medicament stored in the cavity 123 of the reservoir 121 enters the distal end 105 of the needle 103, travels through the needle 103 and into the injection site. Upon releasing the reservoir 123, the compressed spring 161 expands. This action withdraws the needle 103 from the injection site and through the opening 149 such that the proximal end 104 of the needle 103 is again disposed within the septum 181. Preferably, the self-injection device 101 is discarded after being used for an injection. The proximal end 104 of the needle 103 being disposed in the septum 181 prevents an accidental needle stick following the injection.

[0040] As described in the preceding paragraph, the upper housing 131 is rotatable in positions corresponding to a junctional injection (FIG. 6) and a subcutaneous injection (FIG.

7 – 9). In the junctional injection position, the platform indicator may be the numeral (FIG. 3) to indicate needle travel of approximately two millimeters beyond the base of lower housing, which corresponds to the distance required for a junctional injection. The 136 of the upper housing 131 abut the third step 155 when the reservoir 121 is depressed to limit the needle 103 travel to approximately two millimeters, as shown by the distance D<sub>2</sub> of FIG. 6. Preferably, the distance from the outer surface of the base 143 of the lower housing 141 to the outer surface of the base 133 of the upper housing 131 when the reservoir 121 is compressed for a junctional injection is preferably approximately 12 millimeters.

[0041] In the subcutaneous injection position, the platform indicator may be the numeral “4” (FIG. 3) to indicate needle travel of approximately four millimeters beyond the base of the lower housing, which corresponds to the distance required for a subcutaneous injection as shown by the distance D<sub>4</sub> of FIG. 7. The tabs 136 of the upper housing 131 abut the fourth step 155 when the reservoir 121 is depressed to limit the needle 103 travel to approximately four millimeters. Preferably, the distance from the outer surface of the base 143 of the lower housing 141 to the outer surface of the base 133 of the upper housing 131 when the reservoir 121 is compressed for a subcutaneous injection is preferably approximately 10 millimeters. The remaining process for performing an injection is substantially similar to the process described above for the intradermal injection.

[0042] To fill an empty reservoir, the process is similar to performing a subcutaneous injection. The upper housing 131 is rotated to the position corresponding to the subcutaneous injection, as shown in FIGS. 7 – 9. The self-injection device 101 is disposed adjacent a container containing the desired medicament. The reservoir 131 is depressed, such that the proximal

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end 104 of the needle 103 enters the medicament. Releasing the reservoir 131 draws medicament up through the needle 103 and into the cavity 123 of the reservoir 121. The upper housing 131 is then rotated to the locked position, as shown in FIG. 4, to prevent accidental movement of the needle 103. Alternatively, the self-injection device 101 may be provided to a user in a pre-filled condition.

[0043] The compact size of the self-injection device 101 makes it user-friendly, particularly in view of being operable with one hand. Each component of the self-injection device 101 is multifunctional, thereby reducing the number of parts required for assembly. Furthermore, as noted above, after performing an injection the upper housing 131 is rotated back to the lock position, thereby preventing accidental needle sticks and converting the self-injection device 101 into its own self-contained "sharps collector."

[0044] Furthermore, the self-injection device 101 incorporates a safety mechanism to prevent the spread of bacterial and viral pathogens via a needle stick or other accident. As noted above, upon release of the reservoir 121 the needle 103 is withdrawn back into the housing 111, as shown in FIG. 4. The proximal end 104 of the needle 103 is disposed within the septum 181, thereby preventing an accidental needle stick or other accident following injection. The needle 103 is withdrawn passively, such that a user does not need to remember to actively retract the needle, thereby providing a safe self-injection device 101.

[0045] In another exemplary embodiment of the present invention, as shown in FIGS. 10 and 11, a self-injection device 201 is substantially similar to the self-injection device 101. An elongated hollow, septum 281 is disposed within the housing 211. Upon compression of the reservoir 221, as shown in FIG. 11, the upper housing 231 is moved downwardly relative to the housing 211, thereby forcing the needle 203 through the septum 281 and into the medicament 241.



to the lower housing 241, thereby compressing the resilient septum 281. The needle 203 is rigidly fixed to the upper housing 231 such that the needle passes through the septum 281. Upon releasing the reservoir 221, the elasticity of the septum 281 returns the upper housing 231 to its initial position, as shown in FIG. 10. The proximal end of the needle 203 is passively withdrawn into the housing 211, thereby providing a safe self-injection device that prevents needle sticks and other accidents.

[0046] In another exemplary embodiment, as shown in FIG. 12, a self-injection device 301 is substantially similar to the self-injection device 101. An elongated hollow, septum 381 is disposed within the housing 311. A spring 361 surrounds the septum 381 to facilitate returning the resilient septum to its initial position, as shown in FIG. 12, after being compressed. The upper housing 331 moves downwardly relative to the lower housing 321 when the reservoir 321 is compressed. The needle 303 is rigidly fixed to the upper housing 331 such that the needle passes through the septum 381. Upon releasing the reservoir 321, the elasticity of the septum 381 in combination with the spring 361 returns the upper housing 331 to its initial position, as shown in FIG. 12. The proximal end of the needle 303 is passively withdrawn into the housing 311, thereby providing a safe self-injection device that prevents needle sticks and other accidents.

[0047] A self-injection device according to exemplary embodiments of the present invention provides a safe and user-friendly push-button self-injection device, which allows for injection of a medicament, such as a vaccine or insulin. The self-injection device includes passive retraction of the needle to prevent the spread of bacterial and viral pathogens via needle stick or other accident. The desired injection depth is selected and the self-inject

device is placed on the patient's skin. The compressible reservoir is depressed, thereby injecting the needle into the skin and administering the medicament. Alternatively, a reservoir fill mode may be selected, and the self-injection device is placed over a vial containing a medicament to draw the medicament into the compressible reservoir. Release of the compressible reservoir automatically withdraws the needle, thereby providing a safe self-injection device.

[0048] While exemplary embodiments have been chosen to illustrate the invention, it should be understood by those skilled in the art that various changes and modifications may be made therein without departing from the scope of the invention as defined in the appended claims and their equivalents.