PALM ACTIVATED DRUG DELIVERY DEVICE

This application claims the benefits of priority under 35 USC§ 119 and/or §120 from prior filed U.S. Provisional Application Serial Nos. 61/361,983, filed on July 7, 2010, and 61/252,378, filed October 16, 2009, which applications are incorporated by reference in their entirety into this application.

Field of the Invention

The invention generally relates to methods and devices for parenteral drug delivery. The devices provide for assisted manual drug delivery with confirmation of completion of the drug delivery process. The devices provide a system with improved safety and ease of use and audible, or other forms of, feedback to the user to indicate when drug delivery is in process, completed, or both, to avoid one or both of incomplete dosing and wasted medication as well as to provide a system with improved safety and ease of use.

Background of the Invention

For many years, an accepted method for parenteral drug delivery has been through the use of syringe and needle. The syringe contains a quantity of a drug sold either in a pre-filled syringe or introduced into a syringe by drawing the drug into a syringe from a vial or other container. Syringes have been widely accepted due to their low manufacturing cost and simple, effective design. For the user, however, syringes and needles have a number of drawbacks.

One drawback is that many patients have a fear of needles. In instances in which self-medication is required, such as those requiring multiple, daily injections, patients may not administer their medication according to their prescribed regimen due to the fear of needles, the pain that is often associated with an injection, the dexterity

that is required to properly administer a drug via needle and syringe or other, similar factors. For some, that have their vision, dexterity, or awareness impaired, self-administration via needle and syringe may present additional difficulties that can prevent them from receiving their required medication.

There also are safety and disposal concerns associated with needles and syringes not only for the patient, but for those around them, that may result from contaminated needles, accidental punctures, cross-contamination, and the like, in addition to the social stigma associated with a needle and syringe drug-treatment regimen. Despite these drawbacks, however, many patients are encouraged to use needles and syringes to deliver their medication due to the ability to control insertion of the needle and the speed of the drug delivery when the plunger in the syringe is depressed and, therefore, control their perception of pain and discomfort associated with this type of drug injection.

Several advances have been made over the years to help facilitate self-administration of medication. Such advances include smaller needles with improved tip-geometry to reduce the pain. Safety syringes that encase the needle before, after, or before and after use have been used to minimize concerns over accidental punctures with needles. Improved ergonomics in syringe design, as well, have been promoted to reduce the dexterity required to accurately and safely self-administer medication via needle and syringe. Pre-filled disposable devices having a form-factor similar to that of a pen were developed to improve dosing accuracy, and auto-injectors have been used to hide the needle from the patient to reduce fears and safety concerns either by retracting the needle or placing a shield around the needle.

While such advances have improved needle and syringe based drug delivery, ergonomic designs, pens, and auto-injectors all retain a substantial similarity to the

original needle and syringe concept, thus limiting their acceptance by patients who need to self-administer their medication. Current systems employ a form factor that suggests the common "grab and stab" injection technique, wherein the user grips the device in the palm and places the thumb over an activation button.

Current auto-injectors transfer control of drug delivery into the body to a mechanical system. Because such a system is highly dependent on the specific mechanical design of the auto-injector, patients may require specialized training to use the device and still risk inaccurate dosing. This situation is highly problematic when delivering very expensive drugs that might only be administered on a weekly or even more infrequent basis.

The typical method of use of current auto-injectors includes the patient holding the device against the skin for several seconds while the device is in the process of delivering medication. Many users, and the elderly in particular, may experience fatigue in their arm or hand causing them to exert uneven pressure of the device against the skin, or they may remove the device prematurely. Either situation can result in inaccurate dosing, wasted medication, increased discomfort, and the like. Under any of these circumstances, the current devices and methods that include, or evolved from, the traditional syringe and needle system have shortcomings that compromise the efficacy of a prescribed drug regimen.

Finally, as with any health-care related device or service, the cost of any frequently used component of a treatment regimen must be considered. While providing drugs in vials that are used to fill empty syringes at, or about, the time of a patient's medication may provide the least expensive solution, it adds an additional opportunity for waste or loss of an expensive drug. If that drug requires refrigeration, it may experience degradation each time it is removed and reinserted into the refrigeration

device before and after filling the syringe, which can lead to less than expected drug efficacy if the vial contains a quantity of drug that is delivered over a long period of time. While pre-filled syringes offer an advantage in both reliability and convenience, such devices still have the inherent drawbacks previously recited.

With devices such as pre-filled auto-injectors, the device is most commonly manufactured for use with a wide variety of medications, but is tailored to no one medication. Because such devices rely on mechanical systems employing springs to control the injection rate of the drug, many drugs of different viscosity or that require refrigeration and change viscosity appreciably as a result of temperature change, may be delivered too quickly or too slowly for the predetermined spring-force of the auto-injector design. In many instances, too low a spring force may result in incomplete drug delivery, removal of the device before completion of the delivery, or excessive pain and discomfort to the user resulting from a prolonged period during which the injection device is inserted into the body. Too high a spring force, however, can result in drug delivery that is so rapid that it degrades the drug, or may cause injection force pain to the patient caused by rapid delivery of an acidic drug or by inducing a pressure gradient under the skin or in a vein.

Thus, there are many opportunities for advancement in the field of episodic, parenteral drug delivery that could overcome "needle-phobia", reduce pain to the patient, and increase the safety, reliability and efficacy of many drug treatment regimen.

Brief Description of the Drawings

FIG. 1A is a side view of an embodiment of the present invention.

FIG. 1B is a side view of the embodiment of Fig. 1A after cap removal.

FIG. 1C is a side view of the embodiment of Fig. 1B after depression of the interlock button.

FIG. 1D is a side view of the embodiment of Fig. 1C after the needle guard has been retracted, exposing the needle.

FIG. 2A is a side view of the embodiment of Fig. 1D during drug injection.

FIG. 2B is a side view of the embodiment of Fig 2A upon completion of drug injection.

FIG. 2C is a side view of the embodiment of Fig. 2B after the needle guard has been extended, concealing the needle,

FIG. 3 is a depiction of an exploded view of the embodiment of Fig. 1A.

FIG. 4 is a depiction of a cross-sectional view of the embodiment of Fig. 1A.

FIG. 5 is a depiction of a partial cross-sectional view of a portion of the embodiment of Figure 1A, depicting a latch.

FIG. 6 is a depiction of a partial cross-sectional view of a portion of the embodiment of Fig. 1A, depicting a latch.

FIG. 7 is a depiction of a cross-sectional view of the embodiment of Fig. 2A.

FIG. 8 is a depiction of a cross-sectional view of the embodiment of Fig. 2B.

FIG. 9 is a depiction of a cross-sectional view of the embodiment of Fig. 2C

FIG. 10A is a side view of another embodiment of the present invention.

FIG. 10B is a side view of the embodiment of Fig. 10A after cap removal.

FIG. 10C is a side view of the embodiment of Fig. 10B after the needle guard has been retracted, exposing the needle.

FIG. 11A is a side view of the embodiment of Fig. 10C during drug injection.

FIG. 11B is a side view of the embodiment of Fig. 11A upon completion of drug injection.

FIG. 11C is a side view of the embodiment of Fig. 11B after the needle guard has been extended, concealing the needle.

FIG. 12 is a depiction of an exploded view of the embodiment of Fig. 10A.

FIG. 13A is a perspective view of the lower housing of the embodiment of Fig. 10A.

FIG. 13B is a perspective view of the middle housing of the embodiment of Fig. 10A.

FIG. 14 is a depiction of a partial cross-sectional view of a portion of the upper and middle housings of the embodiment of Fig. 10A.

FIG.15 is a depiction of a latching mechanism of the embodiment of Fig. 10A

FIG.16 is a depiction of another latching mechanism of the embodiment of Fig. 10A.

FIG. 17A is a depiction of a cross-sectional view of a portion of the embodiment of Fig. 10A.

FIG. 17B is a depiction of a perspective view of a portion of the lower housing of the embodiment of Fig. 10A.

FIG. 18 is a cross-sectional view of the device of Fig. 10A.

FIG. 19 is an exploded, side view of still another embodiment of the present invention.

FIG. 20 is a depiction of a cross-sectional, side view of yet another embodiment of the present invention prior to use.

Fig. 21A is a perspective view of an alternative design of the lower housing of the embodiment of Fig. 10A.

Fig. 21B is a perspective view of an alternative embodiment of the lower housing of Figure 10A .

Fig. 21C is a cross-sectional view of the lower housing of Figure 21B.

Detailed Description of the Invention and Preferred Embodiments

The following detailed description is to be read with reference to the drawings in which like elements in different drawings are identically numbered. The drawings, which are not necessarily to scale, depict exemplary embodiments for the purpose of explanation only and are not intended to limit the scope of the invention. The detailed

description illustrates by way of example, not by way of limitation, the principles of the invention.

The present invention is a drug delivery device, and methods for its use, which device overcomes many of the limitations and drawbacks of conventional syringes and needles as well as auto-injector-type devices. To overcome the drawbacks and limitations of prior devices and to address the unfilled needs in the art, embodiments of the presently disclosed device and methods include a device that is configured such that the user does not see and cannot touch the needle, reducing needle-phobia and potential for needle contamination. This includes automatic shielding of the needle after delivery of the drug.

Embodiments of the device have an ergonomic form-factor that permits operation one handedly and conveniently allows for alternate site injections, such as the leg, arm, or abdomen. In embodiments that include a pressure-sensitive triggering, a needle guard latch inhibits movement of the needle. In this manner, the device includes a safety mechanism that will not allow the needle to be exposed if it is not pressed against the injection site.

In Figs. 1A-1D is illustrated one embodiment of the device of the invention that includes a window 104 to view the drug prior to use. A colored indicator may appear in the window after the device has been used, to provide a visual indication to the user of whether the device's drug has been spent. Further, after the drug is delivered, increased safety and reduction in the possibility of accidental needle punctures is provided.

To ensure that the user is aware of the status of the drug delivery and whether it is completed, this embodiment of the invention includes pawls and ratchets, such as those illustrated by the pawl 117 and ratchet 116 shown in Figs. 4 and 7, that engage to

produce one or more audible clicks when the injection is completed. Such a mechanism may signal the user that the dose has been delivered and the device can be removed from the skin, preventing premature withdrawal of the device from the injection site. Thus, the user actively participates during the entire delivery process, unlike conventional auto-injectors for which the user may need to wait several seconds for an assurance that the full dose has been administered.

To provide greater feedback to the user, the disclosed system of pawls and ratchets also provides audible clicks and motion of the device during delivery to indicate that the injection is progressing. In yet another embodiment, a louder click at the end of delivery alone or in combination with a visual indicator provides l feedback confirming that the delivery is completed.

Moreover, the present invention has a friendly, unintimidating design and method of operation, unlike conventional needle safety devices and auto-injectors, which are reminiscent of syringes and discomforting to the user. Additionally, unlike conventional auto-inserters, the user controls insertion of the needle and injection of the drug as described hereinafter.

In Figures 1 through 9 are shown an exemplary device of the of the invention. In Figs. 1A through 1D is shown an embodiment of the device in various stages leading up to injection of the drug and in Figs. 2A through 2C is shown the embodiment during and after injection of the drug. Figure 1A shows the device 100 in its pre-use configuration as it may be received by the user. In this relaxed position, upper housing 101 partially overlies the proximal or uppermost portion of lower housing 102. In describing the various embodiments of the device, the term proximal is used in relation to the bottom surface of the device. For example, in Fig. 1B, proximal is used in relation to bottom surface or bottom 131 of device 100.

As shown, the device's outwardly visible features include upper housing 101, lower housing 102, cap 103, window 104, interlock button 105, grip ring 106, bottom edge 111 of the upper housing 101 and dose indicator 107. Figure 3 is an exploded view of the components of this embodiment of the invention.

A preliminary step in using the device is to remove cap 103, which is removably attached to lower housing 102, as shown in Fig. 1B. Removing the cap 103 simultaneously removes needle shield 113 and exposes needle guard 108. Window 104 and needle guard slot 109, each of which are preferably present on both sides of the device, allow the user to view and inspect an internally housed syringe 118 and its drug contents.

In use, the device is grasped by placing the palm of the hand over the top of the upper housing 101, similar to how one grasps a floor- mounted, automotive gear shift. Grip ring 106 provides a visual cue to the user on how to grasp the device. In one embodiment, grip ring 106 is covered, or coated, or made of a suitable elastomeric material including, without limitation, neoprene rubber, urethane, polyurethane, silicone, natural rubber, thermoplastic elastomer ("TPE"), or combinations thereof to provide a non-slip and comfortable gripping surface.

The user presses the device, by downward pressure of the palm on grip ring 106 and interlock button 105, against the body at the desired injection location, typically the top or side of the upper leg, the abdomen, or the side or back of the upper arm. The pressure of the palm on interlock button 105 causes it to deflect downwardly, as shown in Fig. 1C, which in turn unlatches needle guard latch 124, shown in Fig, 5, allowing the needle guard 108 to slide upwardly, and exposing needle 110 (note that some device components have been removed from Fig. 5 for illustration purposes). Needle guard

latch 124 is formed integrally with a portion of the distal end of upper housing sleeve 120. Upper housing sleeve 120 is a hollow cylinder a portion of which resides in the upper housing 101 and portion of which resides in lower housing 102 when the device is in the relaxed position. Upper housing sleeve 120 is fixedly attached to upper housing 101 and performs latching functions and acts to trap biasing element 119 against lower housing 102 as described in more detail below.

Needle guard latch 124 includes inwardly, with respect to the longitudinal center axis A-A' of the device, ramped surface 127 and stop 130 at its uppermost end. To unlatch the needle guard latch 124, an outwardly ramped surface 128, complementary to surface 127, that forms the distal end of interlock button extension 123, engages ramped surface 127 on the needle guard latch 124. Engagement of surfaces 127 and 128 causes the needle guard latch 124 to deflect outwardly, with respect to the center axis, removing stop 130 from blocking the upward movement of needle guard 108. The latching mechanism and needle guard 108 are preferably configured so upward movement of needle guard 108 is prevented unless the interlock button 105 is fully depressed. This protects the needle from contamination and damage due to contact with other surfaces, protects the user from accidental needle punctures, and shields the needle from view.

As the user continues to press downwardly on upper housing 101, needle guard 108 moves upwardly, exposing and allowing needle 110 to penetrate the user's skin, stopping when bottom surface 131of the lower housing 102 is substantially flush against the skin. Once needle guard 108 passes beyond stop 130, the user may release interlock button 105, or chose not to, without affecting the remaining injection steps. When interlock button 105 is released, resilient member 121, returns interlock button 105 to the up position. Movement guide 132 acts to ensure that interlock button travels straight up and down.

The needle insertion process described herein gives control of insertion to the user. This feature allows the user to take advantage of a commonly used method often employed by insulin-dependent diabetics: if the needle is brought into contact with the skin and held there without piercing the skin, after a few seconds the user will no longer feel the presence of the needle, at which point the needle can be inserted pain free by increasing the pressure applied to the needle.

After needle 110 has been inserted into the user, the injection process typically begins, as shown in Figs. 2A through 2C. With reference to Figure 6, aA housing latch 122 that is a part of lower housing 102 is shown in close-up detail and prevents the upper housing 101 from moving with respect to the lower housing 102 in the device's pre-use state (note that some device components have been removed from Fig. 6 for illustration purposes). When needle guard 108 has completed its upward travel, ramped surface 133 on needle guard 108 contacts a ramped portion of surface 134 that forms the end of housing latch 122, causing the housing latch 122 to deflect inwardly, thus allowing the upper housing 101 and upper housing sleeve 120 to move downwardly.

After inserting needle 110 into the body, the user maintains pressure on the upper housing 101. As shown in Figs. 3, 4, 7 and8 a plunger rod 115 pushes on a plunger 112. Plunger rod 115 is connected fixedly to the upper housing 101 and syringe 118 is secured to or held in a cylinder formed within lower housing 102. Thus, when the upper housing 101 moves downwardly with respect to and over the lower housing 102, a drug inside the syringe 110 is delivered through the needle 110 to the patient by the downward movement of plunger rod 115 and plunger 112 within syringe 118.

After the housing latch 122 is disengaged, a biasing element 119 that surrounds the distal end of upper housing sleeve 120, is freed from a tensioned state to apply a downward force on the upper housing 101 by exerting a downward force on upper housing sleeve 120, which is fixedly attached, at its uppermost end, to upper housing 101. Biasing element 119 also can be used to provide energy for assisting with advancement of plunger rod 115 and plunger 112 with the user providing additional required force resulting in injection of the drug or the energy supplied by the biasing element 119 may be sufficient only to advance plunger rod 15 and plunger 112. In another embodiment of the present invention, biasing element 119 provides sufficient force to inject the drug, without additional force input required by the user, thus providing an injection device in which the needle is manually inserted and the drug is automatically injected. The biasing element may be any component capable of exerting a downward force on upper housing sleeve 120 to the degree desired and may be, without limitation, a spring, a compressed gas actuator, a hydraulic drive, a wax actuator, an electrochemical actuator, a shape memory alloy, and the like and the combinations thereof. In the embodiment depicted in Figs. 1 through 9, the user provides the additional force required to advance the plunger rod 115 and plunger 112 by pressing downwardly on the upper housing 101. Thus, the force required by the user to inject the drug is reduced, in a manner analogous to the way power steering in a car reduces the force required by the driver to turn the steering wheel. Unlike conventional auto-injectors, the user contributes to the force required for injection and the present invention provide the user control over the rate of injection of the drug.

Referring to Figs. 4 and 7, cross sectional views of embodiments of the present invention are shown both before and after delivery of the drug has commenced, respectively. As the drug is being delivered, a pawl 117 which is attached to upper housing sleeve 120 moves along a ratchet 116 that is attached to the lower housing 102. The pawl 117 and the ratchet 116 may serve, at least, the following two functions.

First, separation of upper housing 101 from lower housing 102 by pulling them apart is prevented. Second, the motion of pawl 117 along ratchet 116 produces a soft clicking noise, providing feedback to the user that upper housing 101 is moving and the drug is being delivered. Additionally, and as illustrated in Fig. 8, at the end of travel of upper housing 101, pawl 117 may be configured to engage a deeper recess in ratchet 116, thereby producing a louder clicking sound, which can provide an audible signal to the user that end of travel has been reached and the drug has been fully delivered, and further locking the upper housing 101 in place to prevent resetting or reuse of the device.

Referring to Figs. 2B and 8, when the drug is completely injected and upper housing 101 is at the end of its travel, bottom edge 111 of upper housing 101 covers dose indicator 107. Dose indicator 107 is a circumferential, colored ring at the distal portion of lower housing 102. This provides a visual cue to the user that the drug delivery has been completed.

Prior to use, the patient can view the drug through window 104 to inspect it for clarity and particulates. After use, the plunger 112 can be viewed in the window 104, indicating that the device has been used. Alternatively, the window can be designed such that the plunger rod 115 as well is visible after the injection is complete. The plunger 112 and the plunger rod 115 can be brightly colored to provide a clear indication to the patient that the device has been used.

Referring to Figs. 2C and 9, after completing the injection, the user removes device 100 from the skin, and needle guard return element 114 causes needle guard 108 to extend over needle 110, protecting the user and others from accidental needle punctures. Needle guard return may be any element capable of causing needle guard 108 to extend over needle 110 including, without limitation, a spring, a compressed gas

actuator, a hydraulic drive, a wax actuator, an electrochemical actuator, a shape memory alloy, and the like and the combinations thereof. Once needle guard 108 is fully extended, a needle guard lock 125 engages a slot in needle guard 108, preventing the needle guard 108 from retracting. Needle guard lock 125 is a cantilever latch extending inwardly from the inner surface of upper housing sleeve 120. Lower housing rib 126, a part of the lower housing 102, may be configured to prevent the needle guard lock 125 from engaging the slot in the needle guard 108 prematurely during delivery by blocking the slot. In another embodiment of the present invention, needle guard 108 may extend and lock in place if device 100 is removed before delivery is complete, to prevent reuse, or sharing of the device.

With the assisted delivery approach offered by the present invention, the user is actively engaged during the entire delivery process. This is distinguishable from the activation process for conventional auto-inserters, in which after pressing the button, the user passively waits, for several second, for the drug to be delivered, sometimes wondering whether the injection is in process or not.

The assisted activation approach of the present invention has the additional advantage that it reduces development time and cost associated with modifying the injection device for delivering different drugs because the user controls delivery speed by varying the force applied to the upper housing 101. If the plunger is slightly stuck, the user can apply a little more force, unlike conventional auto-injectors that must be designed for worst case force requirements, that vary depending on the drug, cartridge, plunger, needle, and friction in the mechanism.

In another embodiment, the interlock button 105 and the interlock spring 121 can be omitted from the design. In this embodiment, the upper housing 101 is free to move downwardly before hitting a stop. This movement is used to unlock the needle

guard 108 using a mechanism similar the interlock mechanism described above, allowing the needle guard 108 to retract. Once the needle guard 108 is fully retracted, it may disengage another latch that allows the upper housing 101 to discontinue moving downwardly and inject the drug in a similar manner as is described above.

In Figs. 10 through 18 is depicted yet another embodiment of the invention. In Fig. 10A is shown device 200 with upper housing 205, lower housing 202 and middle housing 201 therebetween. Upper housing 205 includes grip cap 228. In the relaxed position, upper housing 205 partially overlies the proximal, portion of middle housing 201. The distal-most portion of middle housing 201 is fixedly seated in lower housing 202. Also shown in Fig. 10A are upper housing bottom edge 211, travel ridge 216, and window 204. Window 204 preferably is seated within the proximal portion of lower housing 202. A second window, not shown, preferably is present on the device on the side opposite of window 204.

Cap 203 is removably attached to lower housing 202 and, in Fig. 10B, is shown removed from device 200 to expose needle shield 213, needle shield clamp 217 and needle guard 208. During removal of cap 203, needle shield clamp 217 grabs and simultaneously removes needle shield 213 exposing needle guard 208 to the user. When the device user presses the needle guard 208 against the skin, this action causes needle guard 208 to slide upwardly exposing needle 210, as shown in Fig. 10C.

Figure 12 is an exploded view of device 200. Grip cap 228 includes grip cap assembly pins 230 that fixedly secure grip cap 228 on upper housing 205. Assembly pins 230 mate with holes 242 in upper housing 205. Preferably, assembly pins 230 are square in cross-section with rounded corners providing an interfering surface between the corners of assembly pins 230 and holes 242. Guides 233 and plunger rod 215, which are integral with and extend downwardly from the inner surface of grip cap 228 as

shown. Plunger rod 215 includes a damper 221 at its distal end. Also shown are syringe 218 with plunger 212 and needle shield 213.

In a preferred embodiment, the external surface of grip cap 228 is coated with or formed from, or the entirety of grip cap 228 is formed from, a material capable of providing a soft, non-slip grip for the user. Suitable materials for coating or forming the grip cap include, without limitation, elastomeric materials such as neoprene rubber, urethane, polyurethane, silicone, natural rubber, TPE and the like and combinations thereof.

Upper housing 205 includes click latch 220, handle rib guide 238, and bottom edge 211. For click latch 220, as well as the other latches used in the device, preferably at least two latches are used and the same latches are symmetrically positioned with respect to each other to facilitate smooth movement and operation of the device.

Middle housing 201 is shown in Fig. 12 with body 207 and handle guide slots 239 on the external surface of the proximal portion of body 207. When the device is in use, handle rib guides 238, which are an integral part of upper housing 205, engage with and slide within handle guide slots 239, maintaining smooth and controlled motion of upper housing 205 during drug delivery.

Body 207 may serve as a dose indicator because, as the device is activated, upper housing 205 descends over body 207. When the complete medication dose has been delivered, body 207 is fully obscured by upper housing 205 as shown in Figure 11C. Preferably body 207 is colored, more preferably with a bright color, or is patterned to provide easily viewed visual feedback to the user that the dosing is progressing or has been completed. Optionally, a scale may be included on body 207 to visually quantify the amount of drug that has been delivered or remains to be delivered .

With reference to Fig. 13, middle housing 201 also includes grip latches 224, click latch capture slots 236, and needle guard latch 237. Grip latch 224 is a generally rectangular element movably attached at its distal-most portion to the inner surface 243 of middle housing 201 so that it is capable of movement outwardly toward inner surface 243 upon application of force. Grip latch 224 also includes a stop surface 245 and a triangular shaped stop 244 extending inwardly toward the device's center from one corner of its topmost portion. In the device's resting, pre-use position grip latch 224 prevents upper housing 205 from moving with respect to middle housing 201 due to stop 245 interfering with the downward travel of guides 233 of grip cap 228.

With reference to Figs. 12 and 13, lower housing 202 is shown with lower housing base 206, end of travel ridge 216, window 204, housing latch 229, guide slots 227 and syringe retainer clip 235. Cap 203 removably attaches to lower housing base 206 via cap retainer ring 234. In use, lower housing base 206 contacts the user's skin and, thus, preferably is made of any of the soft flexible materials suitable for use for grip cap 228.

Window 204 provides an opening in lower housing 202 for viewing of the contents of syringe 218. Window 204 is positioned such that the bottom of syringe 218 is visible to the user allowing the user to verify that plunger 212 has reached the end of its travel to the bottom of the syringe. Window 204 may be any convenient size and shape and preferably is oblong in shape with its long axis aligned with the long axis of the device and syringe so that the desired length of the syringe is exposed to view.

Guide slots 227 maintain the alignment of three different components: guides 233 of grip cap 228; grip latch release 231; and needle guard extensions 241. Guide slots 227 ensure smooth activation of the device by maintaining alignment and vertical

travel of upper housing 202 and needle guard 208 and reliable latching and unlatching of grip latch 231. Housing latch 229 extending outwardly secures middle housing 201 to lower housing 202 by engaging a recess, that is not shown, in inner surface 243 of middle housing 201. In non-reusable embodiments of the device, the shape of latch 229 and the recess are such that the middle and lower housing cannot be separated. For reusable embodiments, the recess and latch are configured to enable the middle and lower housing to be pulled apart.

Referring to Fig. 12, needle guard 208 includes needle guard slot 209 formed on one side by grip latch release 231 and the other side by needle guard extension 241. Grip latch release 231 includes ramped surface 240. Referring to Figs. 14 and 15, ramped surface 240 of grip latch release 231 faces outwardly and, as grip latch 231 travels upwardly, engages ramped surface 244 of grip latch 224, which faces inwardly, causing grip latch 224 to deflect outwardly, removing the obstruction to the downward movement of guide 233 and 205.

Needle guard slot 209 permits window 204 to be used to view the syringe and plunger as the plunger acts on the syringe at the end of the plunger's downward stroke. Additionally, needle guard return 214 lies within and at the bottom of a space formed by grip latch release 231 and needle guard extension 241.

An inventive aspect of the device 200 is the way in which syringe 218 is suspended inside the device. With reference to Figs, 12, 13, and 17, syringe 218 is held between needle shield 213 and damper 221, each of which are flexible components, to protect syringe 218 in the event device 200 is dropped or otherwise mishandled. When the device is assembled, syringe 218 is loosely held within cavity 246 of lower housing 202 by retainer clips 235. Depending on the volume of medication within syringe 218, when the device is in used, there may be some travel of upper housing 205 before

damper 221 contacts plunger 212 and, during this initial downward travel, damper 221 acts as an air piston to compress the air in the gap formed between the end of plunger rod 215 and plunger 212, which provides a rate-dependent resistance to motion to the initial downward motion of grip. When damper 221 moves fast, air cannot escape quickly enough to reduce the build-up of air pressure. Damper 221 may optionally include through-holes, that are not shown, therein to allow air to leak past damper 221. Alternatively, a friction-based resistance from the damper without pressure build-up, use a damper in which there is no leak and no rate dependence, or combinations thereof may be used. Upon contact of damper 221 with plunger 212, damper 221 collapses inwardly towards plunger rod 215 reducing the friction between damper 221 and the inside surface of cavity 246.

With reference to Figs. 10 and 11, when the user desires to use device 200, the user removes cap 203 from lower housing 202, which action simultaneously removes needle shield 213 and exposes needle guard 208. The user grasps device 200 by upper housing 205, places the palm of the hand over grip cap 228 and presses downwardly on grip cap 228 while holding the device 200 against the desired injection site on the body, which pressing action causes needle guard 208 to slide upwardly exposing needle 210. Continuing application of pressure to grip cap 228 results in needle 210 penetrating the user's skin and sub-dermal tissue, stopping when lower housing base 206 contacts the skin surface or when the rim 245 reaches of needle guard 208 reaches the end of its travel within lower housing 202.

With reference to Fig. 15, when needle guard 208 reaches the end of its upward travel within lower housing 202, ramped surface 240 of grip latch release 231 contacts the oppositely facing and complementarily ramped surface 244 of grip latch 224 of middle housing 201 causing grip latch 224 to deflect towards the inner wall 243 of middle housing 201. This action removes stop surface 245 of grip latch 224 from

interfering with the downward travel of guide 233 of grip cap 228 freeing guide 233 and allowing upper housing 205 to move downwardly and over middle housing 201.

When upper housing 205 moves downwardly, the medication inside of syringe 218 is delivered through needle 210 as plunger rod 215 and damper 221 of grip cap 228 push downwardly on syringe plunger 212. At the end of the medication delivery, body 207 is substantially completely covered by upper housing 205 and bottom edge 211 of upper housing 205 has mated with the complementarily shaped travel ridge 216 of lower housing 202. Also, plunger rod 215, damper 221, and plunger 212 are clearly visible within window 204. All of these features provide the user with visual confirmation that the drug has been delivered and the hard stop of bottom edge 211 against travel ridge 216 provides a tactile confirmation to the user.

Additionally, a click mechanism is activated at the end of drug delivery to provide audible feedback. With reference to Fig. 14, click latch 220 is deflected outwardly when ramp 247 thereof contacts and slides past the top of middle housing 201. When the ramp 247 moves sufficiently far downwardly, ramp 247 aligns with click latch capture slot 236 and the ramp 247 slips into capture slot 236, which slot extends through the wall at the proximal portion of middle housing 201, and snaps against the outer surface of body 207 of middle housing 201 creating a clicking sound. In non-reusable versions of the device, click latch 220 is permanently captured by capture slot 236 and cannot be reset. In a preferred embodiment, two click latches 220 are positioned at positions 180 degrees opposite of each other in order to provide smooth activation of the device and to enhance the clicking and latching functions.

As the user removes device 200 from the skin, needle guard return 214, shown in Fig. 12 as a spring, that was compressed by pressing of device 200 against the user's skin, expands causing needle guard 208 to extend downwardly over needle 210

protecting the user from accidental punctures. In addition to a spring, the needle guard return may be a compressed gas actuator, a hydraulic drive, a wax actuator, an electrochemical actuator, a shape memory alloy, and the like and the combinations thereof. When needle guard 208 is fully extended, needle guard retainer 232 engages stop 248, shown in Figure 13, on lower housing 202 preventing needle guard 208 from separating from lower housing 202. In Fig. 16 is shown needle guard latch 237 moveably attached at its distal end to the inner surface 243 of middle housing 201. When needle guard 208 is upwardly traveling, needle guard latch 237 is deflected outwardly on contact with the outer surface of guide 233 or of needle guard extension 241. When needle guard 208 travels downwardly and extends to cover needle 210, needle guard latch 237 slips over the top of needle guard extension 241 preventing needle guard 208 from again retracting.

Prior to use, extension guides 233 of grip cap 228 retain needle guard latch 237 in an outwardly deflected position allowing needle guard 208 to retract for insertion of needle 210. Two needle guard retainers 232 and needle guard latches 237 preferably are used and are located 180 degrees apart around the central axis of the device 200. If the device 200 is removed from the skin before delivery of medication is completed, needle guard 208 will extend to cover needle 210 and locks to prevent reuse of the device. In an alternative, reusable embodiment, needle guard 208 extends, but does not lock in place in the event device 200 is removed from the skin before delivery of medication is completed.

Figure 19 is a depiction of an alternative, reusable embodiment of device 200 in which upper housing 205 and middle housing 201 are separable from lower housing 202. In this embodiment, the user separates the middle and lower housings, inserts syringe 218 into the lower housing and then reattaches the middle and upper housings.

In Figure 20 is depicted yet another alternative embodiment of device 200 in which an assist drive 219 is included. Assist drive 219 may find its greatest utility in delivering viscous drugs. The assist drive 219 applies a force between upper housing 205 and middle housing 201 exerting a downward force on upper housing sleeve 120. This reduces the amount of downward force the user must apply to grip cap 228 in order to inject the drug. Assist drive 219 may be a spring, a compressed actuator, a hydraulic drive, a wax actuator, an electrochemical actuator, a shape memory alloy or the like or combinations thereof. Alternatively, assist drive may provide sufficient force to inject the drug, without additional force input required by the user, thus providing an injection device in which the needle is manually inserted and the drug is automatically injected in a manner similar to a conventional auto-injector.

In Figure 21 is depicted an alternative embodiment of lower housing 202 of device 200 in which a resettable clicking mechanism for a reusable device is included. In this embodiment, guide slots 227 engage guide 2225 of clicker 222. Clicking device 222 is biased by needle guard return 214. To set clicking device 222, the user presses down on one of clicker guides 225 until clicker latch 226 extends over clicking device 222 holding it down. When grip cap 228 moves downwardly, at the end of travel, guide 233 contacts a ramped surface on clicker latch 226 causing it to deflect inwardly and releasing clicker 222 to travel upwardly under the force of needle guard return 214. A click sound is generated when click surface 223 of clicker 222 contacts lower housing 202 signaling that the drug has been completely delivered. The compressing of needle guard return 214 is increased when needle guard 208 is retracted during injection of the drug, increasing the force applied to the clicking device and the volume of the click sound. Alternatively, the click mechanism can be reset automatically when the user attaches the upper housing to the lower housing upon loading a new syringe into the device.

Additional embodiments of the present invention can be envisioned, but are not included in the attached figures. This includes a multiple-dose design in which one or both of the upper and middle housings rise to a partial height and deliver a partial syringe when depressed by the user.

5

Claims

What is claimed is:

1. A device for administering medication, comprising:

a lower housing having a bottom surface and a syringe containing a medication therein;

a middle housing comprising a body;

an upper housing comprising a cap and a plunger rod attached to the upper housing, the upper housing being moveably attached to the middle housing;

wherein when substantially all of the medication is delivered, the upper housing substantially completely covers the lower housing body.

2. The device of claim 1, wherein the lower housing further comprises a needle guard, wherein the needle guard moves upwardly to expose a needle when the lower housing bottom surface is pressed against a skin surface.

3. The device of claim 2, wherein the needle guard further comprises a needle guard return capable of extending the needle guard over the needle when the device bottom is removed from a skin surface.

4. The device of claim 1, wherein the lower housing further comprises a first surface at its proximal end, which first surface is complementary to and mates with

a second surface that comprises the distal end of the upper housing when delivery of the medication is substantially complete.

5. The device of claim 1, wherein the lower housing further comprises at least one window therein through which the distal end of the syringe is visible.

6. The device of claim 1, further comprising an assist drive capable of applying a downward force on the upper housing.

7. The device of claim 1, wherein the upper housing further comprises a cylindrical sleeve therein and fixedly attached thereto, wherein the distal portion of the cylindrical sleeve is housed within the middle housing, the distal portion including an assist drive.

8. A device for administering medication, comprising:

a lower housing configured to fixedly contain a syringe having a needle attached thereto;

an upper housing moveably attached to the lower housing and having a plunger rod attached thereto;

a biasing element for producing a biasing force for moving the upper housing toward the lower housing;

wherein, the biasing force of the biasing element is insufficient to move the upper housing relative to the lower housing, when a syringe having a quantity of fluid therein is present in the lower housing, without the application of an external force against the upper housing.

9. The device of claim 8, wherein the biasing force of the biasing element spring is set in relation to the viscosity of the medication intended for delivery.