NEEDLE-FREE INJECTOR

FIELD OF THE INVENTION

The present invention pertains to the field of needle-free injectors.

BACKGROUND

Injections of medicaments are typically carried out using needle-containing injectors. There are a variety of problems associated with needle-containing injectors including cross-contamination of subjects receiving an injection, the pain associated with such injections and the potential for the needles to break, and dislodge, within a subject being injected. The breakage of a needle within a subject can be not only detrimental to the health and well-being of the subject, but can also have significant economic impact.

Increasingly, efforts have been directed to developing needle-free injectors, in an attempt to avoid problems associated with needle-containing injectors in current use. Typically, such needle-free injectors are powered by an external gas supply so to provide sufficient energy to drive the liquid through the skin. The requirement of an external gas supply can be disadvantageous for the user, as it can be cumbersome and not amenable for use within an enclosure such as an office, laboratory, barn or the like. It can also be inconvenient to store these types external power supplies. Additionally, previous needle-free injectors are typically complicated in design, which in turn results in increased cost of manufacture.

There remains a need, therefore, for improved needle-free injectors.

This background information is provided for the purpose of making known information believed by the applicant to be of possible relevance to the present invention. No admission is necessarily intended, nor should be construed, that any of the preceding information constitutes prior art against the present invention.

SUMMARY OF THE INVENTION

An object of the present invention is to provide a needle-free injection device. In accordance with one aspect of the present invention there is provided a needle-free injection

device for delivering a medicament under pressure from a dosing reservoir through an outlet orifice for administration to an animal and/or human, of the type comprising a plunger slidably received in said dosing reservoir and movable in a forward direction for expelling said medicament through said orifice, the improvement comprising an actuating device disposed on said needle-free injection device, said actuating device comprising: a gas tight chamber; piston and rod assembly slidably received in the chamber and movable between a forward position and a rearward position; a gas charge in the chamber for urging the piston and rod assembly to the forward position; means for moving the piston and rod assembly against the gas charge into the rearward position; and a trigger for releasably retaining the piston and rod assembly in the rearward position, whereby activating the trigger causes the piston and rod assembly to be released for movement by the gas charge to the forward position so as to impact the plunger, directly or indirectly, with a force sufficient to cause the plunger to move in the forward direction to expel the medicament through said outlet.

In accordance with one embodiment of the present invention the circumference of the piston of said piston and rod assembly defines an outer edge that is in contact with the interior surface of said gas tight chamber such that the piston defines an extension portion and a compression portion of said gas tight chamber.

In accordance with another embodiment of the present invention the needle-free device comprises a gap-coupling connecting the rod of the piston and rod assembly to the plunger, wherein said gap-coupling is configured to maintain a gap-distance between said rod and said plunger when said piston and rod assembly is in said rearward position. Preferably the gap-coupling comprises a first end for removable attachment of the gap-coupling to said rod; and a second end for sliding engagement with the plunger.

In accordance with a specific embodiment of the present invention the device includes a manual means for moving the piston and rod assembly against the gas charge, which comprises: (a) a handle pivotally connected to said needle-free injection device and pivotable from a first closed position to a second open position; (b) a push rod pivotally attached to said handle; and (c) an actuating member operatively associated with the rod of said piston and rod assembly and configured to move in response to engagement with the

push rod, whereby when said handle is moved from said first closed position to said second position said push rod engages said actuating member and when said handle is returned to said closed position a pushing force is transferred to said push rod, which in turn transfers the pushing force to said actuating member to move said piston and rod assembly from said forward position to said rearward position.

In accordance with an alternate embodiment of the present invention, the manual means comprises a handle pivotally connected to said needle-free injection device and pivotable from a first closed position to a second open position; an actuating member operatively associated with the rod of said piston and rod assembly; and a force transfer means for transferring force applied to the handle to a gear assembly operatively associated with said handle, whereby when said handle is moved from said first closed position to said second open position said gear assembly transfers force generated by movement of the handle to said actuating member to move said piston and rod assembly from said forward position to said rearward position.

Alternatively, the means for moving said piston and rod assembly is a motorized means, for example a DC or AC power supply.

In accordance with another embodiment of the present invention, the needle-free injection device further comprises a gear assembly driven by a motor; and an actuating member operatively associated with the rod of said piston and rod assembly, whereby said motor ransfers a force to said gear assembly, which transfers the force to said actuating member to move said piston and rod assembly from said forward position to said rearward position.

In accordance with another specific embodiment of the present invention the trigger comprises a triggering lever having a first end and a second end and being pivotable about a pivot member and connected at said first end to said push rod, whereby when a downward force is exerted on said second end of said triggering lever it pivots about said pivot member and said first end is raised causing said push rod to disengage said actuating member such that said piston and rod assembly moves from said rearward position to said forward position.

In accordance with another aspect of the present invention, there is provided a method of injecting a medicament into an animal/human, comprising: (a) providing an actuated needle-free injection device, as described herein and having a medicament within said dosing chamber; (b) placing the outlet orifice of the injection device against said animal at a site for administration; and (c) triggering said injection device such that said medicament is expelled through said outlet orifice.

In accordance with another aspect of the present invention, there is provided a kit for the use of a needle-free injection device as described herein, comprising: (a) the needle-free injection device; and (b) instructions for the use thereof.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1A is a photograph of a needle-free injection device according to one embodiment of the present invention and Figure 1B is a photograph of a needle-free injection device according to another embodiment of the present invention;

Figure 2 is a cross-sectional view of a needle-free injection device according to one embodiment of the present invention;

Figure 3 provides three cross-sectional views of an actuation device in three stages of operation of a needle-free injection device according to one embodiment of the present invention. Figure 3A depicts the actuation device before being mounted in the housing of the needle-free injection device. Figure 3B depicts the actuation device mounted in the housing of the needle-free injection device, wherein the actuation device is in an uncharged condition. Figure 3C depicts the same actuation device as depicted in Figure 3B after charging of the device by the user, such that the piston and rod assembly is in the rearward position.

Figure 4 is a cross-sectional view of a gap-coupling suitable for use in a needle-free injection device according to one embodiment of the present invention. Figure 4A depicts an exploded view of the plunger, gap-coupling and connector. Figures 4B and 4C depicts the plunger slidingly received within the gap-coupling, the gap-coupling is attached to the connector, which is in turn connected to the rod.

Figure 5 is a cross-sectional view of a manual means for moving the piston and rod assembly against the gas charge in a needle-free injection device according to one embodiment of the present invention. Figures 5A and 5B depict the handle in the first closed position and second open position, respectively.

Figure 6 is a photograph of an example of the manual charger depicted in Figure 5;

Figure 7 is a photograph of an example of the manual charger depicted in Figure 5;

Figure 8 A and B are cross-sectional views of a needle-free injection device (A) and a hand-held unit (B) according to one embodiment of the present invention;

Figure 9 is a cross-sectional view of a needle-free injection device according to one embodiment of the present invention;

Figure 10 is a graphical representation of the pressure pattern observed after triggering the injection device of the present invention.

Figure 11 is a side view of one embodiment of the needle-free injector of the present invention;

Figure 12 is a cross-section side view of the needle-free injection device depicted in Figure 11;

Figure 13 is a partial perspective view of the needle-free injection device depicted in Figure 11;

Figure 14 is a partial perspective view of the needle-free injection device depicted in Figure 11;

Figure 15 is a partial perspective view of the needle-free injection device depicted in Figure 11;

Figure 16 is a perspective, partially exploded view, of the needle-free injection device depicted in Figure 11;

Figure 17 is a side, partially exploded view, of the needle-free injection device depicted in Figure 11;

Figure 18 is a perspective, partially exploded view, of the needle-free injection device depicted in Figure 11;

Figure 19 is a side, partially exploded view, of the needle-free injection device depicted in Figure 11;

Figure 20 is a longitudinal cross sectional view the needle-free injection device depicted in Figure 11;

Figure 21 is a partial perspective view of the needle-free injection device depicted in Figure 11;

Figure 22 is a partially transparent side view of a needle-free injection device according to an alternative embodiment of the present invention;

Figure 23 is a side view of the needle-free injection device depicted in Figure 22;

Figure 24 is a magnified side view of the needle-free injection device depicted in Figure 22; and

Figure 25 is a magnified side view of the needle-free injection device depicted in of Figure 22.

In the Detailed Description that follows the numbers in bold face type serve to identify the component parts that are described and referred to in relation to the drawings depicting various embodiments of the invention. It should be noted that in describing various embodiments of the present invention, the same reference numerals have been used to identify the same or similar elements. Moreover, for the sake of simplicity, parts have been omitted from some figures of the drawings.

DETAILED DESCRIPTION OF THE INVENTION

As will be explained in more detail below, the present invention provides a needle-free injection device for injecting a medicament under pressure into a human or animal. The device of the present invention comprises some of the features of standard needle-free injection devices including a dosing reservoir for the medicament, and an outlet orifice in the dosing reservoir through which the medicament is expelled for administration to the animal or human. As in certain needle-free injection devices known in the art, the device of the present invention makes use of a plunger slidably received in the dosing reservoir and movable forward for expelling the medicament through the outlet orifice. In the device of the present invention, these features are combined with an actuating device comprising a gas tight chamber having a piston and rod assembly slidably received therein, a gas charge in the gas tight chamber for urging the piston and rod assembly to a forward position, means for moving the piston and rod assembly against the gas charge to a rearward position and a trigger for releasably retaining the piston and rod assembly in the rearward position, such that when the trigger is released, the piston and rod assembly moves to the forward position so as to impact the plunger, directly or indirectly, with sufficient force to move the plunger forward to expel medicament from the dosing reservoir and through the skin of the human or animal being treated.

All or a portion of the needle-free injection device is preferably sized to be portable, for example hand-held, thereby allowing a user to move from subject to subject (e.g., a human or an animal) to perform injections. Alternatively, all or a portion of the needle-free device may be permanently or removably attached to a structure, such as an injection station, thereby allowing the user to bring the subjects to the injection station to receive an injection. In certain applications it may also be beneficial to have only the dosing portion of the device sized to be hand-held by a user. In this embodiment, the actuating portion remains operatively associated with the dosing portion.

Referring to the Figures 1-10, the needle-free injection device comprises a dosing reservoir **16** for receiving a liquid, such as a medicament. Reservoir **16** has a discharge end having an outlet orifice having nozzle **17**, through which the liquid in the reservoir may be

expelled for administration to an animal or human. Optionally, nozzle **17** is removably attached to the discharge end of dosing reservoir **16**, for example via a screw fit. Optionally, reservoir **16** has an inlet opening through which the liquid may be received. Dosing reservoir **16** can be sized to accommodate a range of volumes of liquid. Additionally, dosing reservoir **16** may be removable so as to facilitate the use of reservoirs of varied sizes and/or material suitable for different volumes or different liquids depending on specific applications.

Generally opposite the discharge end of the dosing reservoir is an expelling means for expelling the liquid within the dosing reservoir through the outlet orifice. In one embodiment of the present invention, as seen in Figure 2, the expelling means is a plunger **15** slidably received in dosing reservoir **16** and movable between a rearward position and a forward position. Plunger **15** is sized to fit within dosing reservoir **16** such that when it is moved from the rearward position to the forward position it causes the liquid within dosing reservoir **16** to be expelled. Movement of plunger **15** from the rearward to the forward position is controlled by actuating device **40**.

Actuating device **40** is disposed within a housing **1** of the needle-free injection device. Components of actuating device **40** are typically formed of a durable material, non-limiting examples of which include, steel, stainless steel and/or an alloy. Components of the needle-free injection device are typically formed of a durable material, non-limiting examples of which include, steel, stainless steel, an alloy, carbon fiber and/or composite plastic.

In accordance with one embodiment of this invention, housing **1** is adapted to be hand-held by a user, and is optionally adapted to receive an extension handle **2** via connector **22**. Alternatively, actuating device **40** may be disposed on housing **1**. Dosing reservoir **16** is optionally removably attached to housing **1**, for example, via a screw fit.

In an alternative embodiment, housing **1** is not configured to hand-held by a user but rather to be attached to a belt or held in a backpack, or the like, which is worn by the user. Alternatively, housing **1** is adapted to be removably attached to a structure. In each case,

actuating device **40** remains operatively associated with the dosing portion of the needle-free injection device when in use.

Actuating device **40** comprises a gas tight chamber **4** with a piston and rod assembly **32** reciprocally disposed within chamber **4** and moveable between a forward position and a rearward position. The term "gas tight chamber", as used herein, generally refers to a chamber having a piston and rod assembly reciprocally disposed therein. The gas tight chamber is adapted to minimize or prevent the escape of a pressurized gas, or mixture of gasses, so as to maintain the gas, or mixture of gasses, contained therein in a pressurized state.

Piston and rod assembly **32** includes piston portion **60** and rod portion **30**. The shape of piston **60** generally corresponds to the shape of the interior of gas tight chamber **4**. In a specific embodiment of the present invention, as depicted in Figures 3A, 3B and 3C, the gas tight chamber **4** is substantially cylindrical having an interior with a generally circular cross-section. Piston **60** of piston and rod assembly **32** is generally disk-shaped and the circumference of piston **60** defines an outer edge **62** that is in contact with the interior surface **64** of gas tight chamber **4** such that piston **60** defines an extension portion **E** and a compression portion **C** within gas tight chamber **4**. The circumference of piston **60** may be defined by sealing member **66**, which may be an o-ring. Piston **60** further comprises a through passage (not shown) for fluid communication between extension portion **E** and compression portion **C**. The passage is sized to enable rapid movement of piston and rod assembly **32** within chamber **4** from the rearward position to the forward position. This configuration is similar to that observed in conventional gas-charged springs or shock absorbers, wherein a passage(s) within the piston is sized to dampen or reduce the travel of the piston and rod assembly within the chamber.

In one embodiment, piston **60** has a generally circular passage therethrough having a diameter that is approximately one third (a ratio of 1:3) of the diameter of piston **60**. The skilled worker will appreciate that the ratio of the diameter of the circular passage to the diameter of the piston **60** can be varied. If, for example, the ratio is 1:6, thereby having a smaller passage diameter as compared to the ratio of 1:3 mentioned above, the speed of the

piston and rod assembly **32** would be decreased. This decrease in speed would allow for the use of a gas-charge, which would otherwise be used for a larger animal or humans, for injecting a smaller sized animal or human. In contrast, as the ratio approaches 1:1, the speed of piston and rod assembly **32** would be increased, as compared to the ratio of 1:3 mentioned above. In such a 1:1 configuration, gas-tight chamber **4** is constructed of sufficiently strong material to ensure piston and rod assembly **32** does not breach the end of the chamber **4** when moving to the forward position.

Rod **30** of piston and rod assembly **32** is disposed within chamber **4** and through opening **68** in chamber **4**. Interaction of rod **30** with sealing means **70** positioned about opening **68** of chamber **4** provides a seal so as to minimize or prevent escape of the gas charge from chamber **4**. In a specific embodiment, sealing means **70** is an o-ring.

In accordance with another embodiment of the invention, chamber **4** is provided with reinforcing members **72** positioned adjacent to opening **68**. Reinforcing members **72** act to provide support to the walls of chamber **4** and to rod **30**.

Chamber **4** contains a gas charge for urging piston and rod assembly **32** to its forward position (as shown in Figure 3A). The term "gas charge", as used herein, generally refers to a pressurized inert gas, or a pressurized mixture of more than one type of inert gas, contained within gas tight chamber **4**. Examples of inert gases suitable for use in the actuating device of the needle-free injection device of the present invention include, but are not limited to, nitrogen, carbon dioxide, helium, neon, argon, krypton, xenon, and mixtures thereof. Selection of the inert gas will depend on various factors, including: the application, cost, ease of use, etc. In practice, empirical tests can be used to confirm the suitability of a selected gas or gas mixture. In such tests, the suitability can be determined by measuring the depth of injection achieved in comparison to the depth when injection is performed with a traditional needle (an industry standard) and/or the recommended depth of medicament placement by medicament manufacturers. Advantageously, the inert gas is nitrogen. Conventional means of introducing a gas charge into chamber **4** can be used and are known to the skilled worker.

The pressure of the gas charge within gas tight chamber **4** is greater than that of the surrounding atmospheric pressure, thus urging piston and rod assembly **32** to the forward position (as shown in Figure 3A). Ultimately, selection of the appropriate gas pressure and type of gas will depend on the application of the injection device. Advantageously, the pressure of the gas charge within the gas tight chamber is selected such that the medicament is expelled with a force of from 100 N to 5000 N. As with certain currently used needle-free injection devices, the generated force can be adjusted, for example, by increments of 50 N (e.g., 100 N, 150 N, 200 N ... 4550 N, 5000 N). However, it will be clear to the skilled worker that any force between 100 N and 5000 N can be selected depending on the force required to pierce the skin of the subject. The force can be adjusted by adjusting the pressure of the gas charge.

As piston and rod assembly **32** is moved from the forward position to the rearward position, the pressure of the gas acting to urge piston and rod assembly **32** forward increases. The repulsive force of the compressed gas on piston and rod assembly **32** is related to the pressure of the gas charge and the surface area of piston and rod assembly **32** exposed to the compressed gas.

In accordance with an embodiment of the present invention an actuating device **40** includes a lubricating medium for lubricating the interaction of piston and rod assembly **32** and the interior of chamber **4**. The lubricating medium may also enhance the sealing interaction between rod **30** of piston and rod assembly **32** and o-ring **70** in opening **68** of chamber **4**. The loss of the gas charge and/or lubricating medium from chamber **4** is minimized or prevented due to the sealing interaction of rod **30** and sealing means **70**. It will be appreciated by those skilled in the art that nature of the lubricating medium, if present, depends on the overall application of the actuating device **40**, and the conditions in which it is used. In one example, the volume and viscosity of the lubricating medium is selected such that the movement of piston and rod assembly **32** from the rearward position to the forward position within gas-tight chamber **4** is not significantly dampened by the presence of the lubricating medium. For example, a small volume of light weight oil is less likely to dampen the travel of the piston and rod assembly **32** than a larger volume or a heavier weight oil. In contrast, if the skilled user requires that the velocity of piston and rod

assembly **32** be dampened (which may be necessary if, for example, a high pressure gas-charge is to be used), a greater volume or more viscous oil is used.

When the actuation device is installed in a needle-free injection device, the piston and rod assembly may be slightly compressed, as shown in Figure 3B. This slight compression aids in distribution of the lubrication medium around piston and rod assembly **32**.

In one embodiment of the present invention, the actuating portion and the dosing portion of the injection device are directly attached to one another. In this embodiment, gap-coupling **13** connects rod **30** of piston and rod assembly **32** to plunger **15**. Gap-coupling **13** maintains a gap-distance **X** between rod **30** and plunger **15** when piston and rod assembly **32** is in the rearward position. Gap-coupling **13** is removably attached to rod **30** and is in sliding engagement with plunger **15**. As depicted in Figures 4A, 4B and 4C, plunger **15** is fitted through an opening in gap-coupling **13**, such that plunger **15** is slidingly received within one end of gap-coupling **13**. Gap-coupling **13** is attached at the opposite end to connector **12**, which is, in turn, connected to rod **30**. In an alternative embodiment, gap-coupling **13** is attached directly to piston and rod assembly **32** and no connector is required. It will be apparent to the skilled worker that gap-coupling **13** can be connected to rod **30** and plunger **15** in a variety of ways, provided that the gap-distance **X** is maintained between piston and rod assembly **32** and plunger **15** when piston and rod assembly **32** is in the rearward position. This configuration results in "direct" impact of plunger **15** by piston and rod assembly **32** when it is released for movement by said gas charge to its forward position.

In some instances, it may be desirable for the actuating portion of the injection device to be located apart from the dosing portion (see Figures 8 and 9). This can be advantageous, for example, if the actuating device is heavy and, therefore, it is easier for a user to carry the actuating portion at their waist, back, slung over a shoulder, or the like, in a remote portion **202**. In this embodiment, hand-held portion **200** contains dosing chamber **16**, plunger **15** and nozzle **17**. In such a configuration of the needle-free injection device, transferring means **100** for transferring force generated by movement of piston and rod assembly **32** to said plunger **15** is incorporated into the overall device. This configuration

results in "indirect" impact of plunger **15** by piston and rod assembly **32** when it is released for movement by said gas charge to its forward position. Specifically, activation of the trigger causes piston and rod assembly **32** to be released for movement by said gas charge to the forward position thereby imparting a force to transferring means **100**, which in turn transfers the force to plunger **15**. In such an example, gap-coupling **13** connects transferring means **100** to plunger **15** (Figure 8), or piston **60** of piston and rod assembly **32** to transferring means **100** (Figure 9). Gap-coupling **13** maintains gap-distance **X** between transferring means **100** and plunger **15** (Figure 8), or between rod **30** and transferring means **100** (Figure 9), respectively, when piston and rod assembly **32** is in the rearward position. Transferring means **100** can be in the form of, for example, a closed hydraulic hose, a flexible multi-link cable/shaft enclosed in a casing, or the like.

The appropriate gap-distance **X** is selected to maximize the velocity of piston and rod assembly **32** following triggering of the device and before direct or indirect impact with plunger **15**. This, in turn, maximizes the available force for impact of the liquid at the orifice end of the device. This impact force is important to the operation of the device, since it provides the opening for the medicament to pass through the skin and the subcutaneous tissue. Gap-distance **X** also allows the injector to perform injections in large animals using relatively low pressures because the impact required for piercing skin and subcutaneous tissue is far greater than the pressure required to inject the remaining dosage of the medicament into the desired tissue. This makes the injector safer and much less painful to the subject receiving an injection in comparison to conventional needle-free injection devices. To draw a comparison, when triggered, an injector that operates with one constant pressure during an injection pierces the skin and subcutaneous tissue and delivers the liquid to be injected using the same pressure. If the user moves or slides the orfice end of the device during this process the flesh of the subject can be sliced, as with a scalpel, thus potentially causing severe wounds. By including a gap-coupling **13**, the pressure is delivered in a spike formation where, at impact, the pressure spikes to the desired level to pierce the tissue, but drops to perform the remainder of the injection (See Figure 10).

If gap-distance **X** is too small, piston and rod assembly **32** is unable to reach maximum velocity, the impact is lessened and the force at the orifice available for piercing

is less. If the gap-distance **X** is increased, very little effect on impact pressure results due to the fact that the maximum velocity has already been reached and therefore maximum force had been reached at the orifice end.

In one embodiment of the present invention, gap-distance **X** is a fixed distance. In one example the gap-distance is 3/8 inch. In an alternative embodiment, the gap-coupling is user adjustable such that the gap-distance can be varied depending on the application of the device. In another alternative embodiment, the gap-coupling is integral to rod **30**.

In operation, as piston and rod assembly **32** moves from the rearward position to the forward position it travels gap-distance **X** before the impact end of rod **30** impacts, either directly (Figures 2, 4 and 5) or indirectly, via transferring means **100** (Figures 8 and 9), the rear end of plunger **15**. Plunger **15**, in turn, moves from its rearward position to its forward position within dosing reservoir **16** so as to expel a liquid from dosing reservoir **16** through nozzle **17**.

Actuating device **40** of the needle-free injection device of the present invention further comprises means for moving piston and rod assembly **32**, against the gas charge in gas tight chamber **4**, from its forward to its rearward position. Through use of this means for moving, a user is able to "charge" the injection device in order to make it ready for injection. The means for moving piston and rod assembly **32** may be a motorized or manual means.

In accordance with a specific embodiment of the present invention the means for moving piston and rod assembly **32** are motorized means. Such motorized means may include DC (optionally rechargeable) and/or AC power supplies. In one example, the motor will be removably mounted on its own assembly or within a bracket.

In accordance with an alternative embodiment of the present invention the means for moving piston and rod assembly **32** are manual means. One example of such manual means is depicted in Figure 5. Handle **3** is pivotally connected to housing **1** of the needle-free injection device and is pivotable from a first, closed position (as shown in Figure 5A) to a second, open position (as shown in Figure 5B). Push rod **50** is pivotally attached to handle **3**. Push rod **50** can be fixed in length or can be configured to allow a variation in length. For

example, push rod **50** depicted in Figure 5, includes a threaded member **10** received within a thread receiving body **8**. The length of push rod **50** is decreased or increased by threading or unthreading, respectively, threaded member **10** within receiving body **8**.

Figures 8 and 9 depict an injection device of the present invention comprising a remote portion **202** that is distantly related from hand-held portion **200**. In accordance with this embodiment of the present invention the means for moving piston and rod assembly **32** is a motorized or a manual means, as described above. Furthermore, the motorized or manual means can be attached to either remote portion **202** or hand-held portion **200**.

In operation, movement of handle **3** from the first, closed position (Figure 5A) to the second, open position (Figure 5B) brings push rod **50** into engagement with actuating member **11**. Actuating member **11** is operatively associated with rod **30** of piston and rod assembly **32** such that movement of actuating member **11** causes corresponding movement of piston and rod assembly **32** in order to move it, against the gas-charge, from its forward position to its rearward position. This movement "charges" or actuates the injection device.

In the specific embodiments of the present invention depicted in Figures 1, 2, 4, 5, 6, 7 and 9, actuating member **11** is a attached to gap-coupling **13** via connector **12** and connector **12** is removably attached to rod **30**. In Figure 8, actuating member **11** and connector **12** are removably attached to rod **30** and to means for transferring force **100**, which is in turn attached to gap-coupling **13** via a second connector **212.** Movement of handle **3** from the first, closed position to the second, open position results in the push rod **10** engaging a notch **80** in actuating member **11**. Movement of handle **3** from the second, open position back to the first, closed position transfers a pushing force to actuating member **11** which, in turn, moves piston and rod assembly **32**, via movement of connector **12**, from its forward position to its rearward position. In an alternative embodiment actuating member **11** is directly connected to piston and rod assembly **32**.

Once in the rearward position, piston and rod assembly **32** is held in place by a trigger. The trigger is a mechanism that maintains piston and rod assembly **32** in the rearward position and is user activatable to allow piston and rod assembly **32** to be released

from its rearward position to move to the forward position due to the pressure generated by the compressed gas-charge.

In accordance with one embodiment of the present invention, user activation of the trigger causes disengagement of push rod **50** from actuating member **11**. In the specific embodiment depicted in Figure 2, the trigger comprises triggering lever **5** having a first end **92** and a second end **94** and being pivotable about pivot member **24**. Triggering lever **5** is connected at first end **92** to push rod **50**. When a downward force is exerted on second end **94**, for example by button **7**, triggering lever **5** pivots about pivot member **24** and first end **92** is raised, thus causing push rod **50** to disengage actuating member **11**. Once push rod **50** is disengaged from actuating member **11**, forward movement of piston and rod assembly **32** is committed, that is, there is nothing to stop or slow movement of piston and rod assembly **32** from its rearward to its forward position in response to the compressed gas-charge. In the case of the device comprising remote portion **202** and hand-held portion **200**, user activation of the trigger may be effected on either remote portion **202** or hand-held portion **200** or both. As depicted in Figures 8 and 9, lever **220** is a conventional finger trigger within hand-held portion **200** and is connected to remote portion **202** via trigger cable **206**. A non-limiting example of trigger cable **206** is a steel cable, optionally slidably contained within a plastic housing. It will be apparent to the skilled worked that various types of cables are suitable for use as trigger cable **206**.

In contrast to the injection device of the present invention, previous injectors required that the trigger be depressed during the entire course of the injection. In such injectors, if the user stops depressing the trigger, the injection process ceases. Therefore, these prior devices can result in incomplete administration of the desired dose of the medicament due to user error in using the trigger.

In accordance with one embodiment of the present invention, the injection device includes trigger guard **23**, which is designed to minimize or eliminate the possibility of unintentional triggering of the actuated device.

In accordance with another embodiment of the present invention, the injection device includes a securing latch to maintain handle **3** in the first, closed position until un-latched for

use. The securing latch may comprise a moveable downwardly facing hook on the underside of handle **3** that interacts with an upwardly facing hook on the outer surface of housing **1**. By moving the downwardly facing hook, the securing latch is released and handle **3** can be moved to its second, open position. Alternatively, the securing latch may comprise a slot in handle **3** for receiving a depressible knob on the outer surface of housing **1**. By depressing the knob, the securing latch is released and handle **3** can be moved to its second, open position.

Figures 11 – 21 and 22 – 25 depict needle-free injection devices according to alternative embodiments of the present invention, which include a manual or motorized means for moving the piston and rod assembly from its forward position to its rearward position. In each case, the device includes a means for transferring and/or amplifying the force applied to the injection device for charging the actuating device. In accordance with a specific embodiment of the present invention, the means for transferring and/or amplifying the applied force comprises a gear assembly; examples of which are depicted in Figures 11 - 21 and 22 - 25. Such a gear assembly provides a mechanical advantage to facilitate charging of the actuation device. The actuation device of the needle-free injectors depicted in Figures 11 - 21 and 22 - 25 comprises an actuating member operatively associated with the rod of said piston and rod assembly. The manual or motorized means for moving the piston and rod assembly transfers a force to a gear assembly, which, in turn, transfers, and optionally amplifies, the force to the actuating member to move the piston and rod assembly from the forward position to the rearward position.

As discussed above, actuating device **40** of the needle free injection device of the present invention further comprises means for moving piston and rod assembly **32**, against the gas charge in gas tight chamber **4**, from its forward to its rearward position. The means for moving piston and rod assembly **32** may be motorized or manual means.

Referring to Figures 11 – 21, actuating device **40** is disposed within guide tube **348**, which is connected to dosing reservoir **16** via connector **390**. Connector **390** is a generally open-ended cylinder that has a first end, for removable attachment to guide tube **348**, and a second end, for removable attachment to dosing reservoir **16**. Optionally, connector **390** is

removably attached to guide tube **348** via a threaded connection. Similarly, connector **390** is optionally removably attached to dosing reservoir **16** via a threaded connection.

In an alternative embodiment, connector **390** is removably attached to dosing reservoir **16** via a quarter-turn release mechanism. In such a quarter-turn release mechanism, connector **390** further includes two pins (not shown) projecting from the inner surface of connector **390**. In this example, dosing reservoir **16** includes a generally L-shaped groove in its outer surface. The protruding pins and generally L-shaped groove are configured to slidingly mate with each other when dosing reservoir **16** is inserted into connector **390**, and rotated, such that the pins follow the generally L-shaped groove. In the quarter-turn release mechanism, barrel wave spring **400** is disposed between connector **390** and dosing reservoir **16** so as to urge the connector **390** and dosing reservoir **16** apart, and prevent free rotation of connector **390** and dosing reservoir **16**.

Plunger **15** is disposed within dosing reservoir **16** and is removably attached to gap-coupling **13**. In one example, plunger **15** is attached to gap-coupling **13** by a threaded screw. In another example, plunger **15** is attached to gap-coupling **13** by a quarter-turn mechanism. Gap-coupling **13** is removably attached to rod **30** of piston and rod assembly **32**. Idler pulley **316** is slidingly mounted in guide tube **348** and is attached to gap-coupling **13**.

Charging

As described above, movement of piston and rod assembly **32** from its forward position to its rearward position charges the injection device. In use, the injection device depicted in Figures 11 to 21, is charged by moving idler pulley **316** from a forward position to a rearward position, which in turn moves piston and rod assembly **32** from its forward to its rearward position. Accordingly, in the device depicted in Figures 11 - 21, idler pulley **316** is serving as an actuating member, as described above.

As noted above, a gear assembly provides a mechanical advantage to facilitate charging of the actuator. In accordance with one embodiment of the present invention, an actuating force is applied by the user to manual means for moving the rod and piston

assembly **32**. In the specific embodiment depicted in Figures 11 to 21, the manual means comprises charging handle **300**, which is attached to bracket **364**, which is, in turn, pivotally attached to main shaft **302** by a ratchet mechanism **311**. Charging handle **300** is pivotable from a first closed position (as depicted in Figures 11, 16, 17, 18 and 19) to a second open position (not shown). Main shaft **302** is mounted through gear end **308**, and includes first end **301** and second end **303**. When charging handle **300** is pivoted, charging handle **300** and bracket **364** rotate main shaft **302**.

Ratchet mechanism **311** and pawl **313** that engages ratchet mechanism **311** are configured to permit main shaft **302** to rotate when charging handle **300** is moved from the first closed position to the second open position, and prevent main shaft **302** from rotating when charging handle **300** is moved from the second open position to the first closed position. Other suitable ratchet mechanisms will be well known to the skilled worker and can be incorporated into a needle-free injection device of the present invention.

Main gear **310** is attached to first end **301** of main shaft **302;** main pulley **312** is attached to second end **303** of main shaft **302**. Both main gear **310** and main pulley **312** rotate with main shaft **302**. Cable **314** passes around idler pulley **316,** and includes first end **315** attached to main pulley **312** and a second end (not shown) attached to main gear end **308**. Cable **314** is constructed of steel and/or other suitable material(s).

The gear assembly is operable to move idler pulley **316** from a forward position to a rearward position, and thereby move piston and rod assembly **32** from its forward position to its rearward position.

Main pulley **312** is rotatable from a first unwound position to an second wound position. As main pulley **312** is rotated from the first unwound position to the second wound position, cable **314** winds around main pulley **312** and pulls idler pulley **316**, thereby moving piston and rod assembly **32** from its forward position to its rearward position, against the gas charge in gas tight chamber **4**.

In this example, the trigger is a trigger mechanism that releasably retains piston and rod assembly **32** in its rearward position.

Trigger pivot arm **328** is pivotable about secondary shaft **332** from a locked position to an unlocked position. Triggering gear **326** is mounted on trigger pivot arm **328**; when trigger pivot arm **328** is in the locked position, triggering gear **326** is in gearing relation with main gear **310**. In the locked position, triggering gear **326** rotates as main gear **310** rotates.

Drive gear **330** is mounted on secondary shaft **332**, and is also in gearing relation with trigger gear **326**; as trigger gear **326** rotates, drive gear **330** rotates.

A uni-directional clutch (not shown, but generally indicated at position **336)** allows secondary shaft **332** to rotate when charge handle **300** is moved from the first closed position to the second open position. Thus, uni-directional clutch **336** holds the charge of actuating device **40** by preventing main shaft **302** and secondary shaft **332** from rotating, when charging handle **300** has moved from the first closed position to the second open position.

Repeated movement of charging handle **300** from the first closed position to the second open position, and back, results in the continued winding of main pulley **312**, and movement of piston and rod assembly **32** to the rearward position, against the gas charge in gas tight chamber **4**.

Charging of actuating device **40** continues until the desired charge is achieved. In one example, a dosage ring (not shown) is used to set the desired charge. In this example, the dosage ring is positioned on guide tube **348** and can be locked into place. The dosage ring is user adjustable to set the extent to which piston and rod assembly **32** can be drawn back; therefore, the dosage ring is user adjustable to set the amount of medicament that is ultimately drawn in to the injector, for subsequent injection. The dosage ring may be set to include a wide range of charges, and thus injection volumes. In one example, the dosage ring is adjustable over a range of volumes between about 0.01cc to about 5cc.

When trigger pivot arm **328** is moved to the unlocked position, triggering gear **326** pivots away from main gear **310**, enabling main gear **310** and main shaft **302** to rotate so as to permit main pulley **312** to move from the second wound position to the first unwound position. Movement of main pulley **312** from the second wound position to the first

unwound position permits piston and rod assembly **32** to move from its rearward position to its forward position, due to the pressure generated by the compressed gas-charge.

Trigger pivot arm **328** is operably connected to barrel trigger **356** or finger trigger **354** though a series of trigger levers and a trigger rod. First trigger lever **338** is pivotally attached to trigger pivot arm **328** and second trigger lever **340**. Second trigger lever **340** is pivotally attached to pivot mount **380**. Second trigger lever **340** includes slot **366**. Third trigger lever **342** is pivotally mounted to main gear end **308**, at pivot mount **368**. First end **343** of third trigger lever **342** is slidingly attached to second trigger lever **340** at slot **366;** second end **345** of third trigger lever **342** is attached to fourth trigger lever **344**. Fourth trigger lever **344** is pivotally mounted to third trigger lever **342** at pivot mount **370**, and is attached to first end **307** of main triggering rod **306**.

Main trigger rod **306** is slidingly mounted through trigger rod guides **346,** which are attached to guide tube **348.** Main trigger rod **306** is movable between a forward position to a rearward position. In the forward position, trigger pivot arm **328** is in the locked position; in the rearward position, trigger pivot arm **328** is moved to the unlocked position. Finger trigger linkage **350** has a first end that is attached to main trigger rod **306** and a second end that is attached to finger trigger **354.** Barrel trigger **356** is slidingly mounted on reservoir **16**. Barrel spring **352** urges barrel trigger **356** away from second end **309** of main trigger rod **306**. Actuation of the needle free injector can be accomplished using barrel trigger **356** or finger trigger **354**.

Using barrel trigger **356**, nozzle **17** is pushed onto the body to be injected with enough force to move barrel trigger **356** against barrel spring **352** so as contact and move main trigger rod **306** from its forward position to its rearward position.

Using finger trigger **354**, moving finger trigger **354** from a forward position to a rearward position causes finger trigger linkage **350** to move main trigger rod **306** from its forward position to its rearward position.

Movement of main trigger rod **306** from its forward position to its rearward position causes in fourth trigger lever **344**, third trigger lever **342**, second trigger lever **340** and first

trigger lever **338** to act so as to move trigger pivot arm **328** from the locked position to the unlocked position. As discussed above, movement of trigger pivot arm **328** to the unlocked position allows main gear **310** and main shaft **302** to rotate so as to permit main pulley **312** to move from the second wound position to the first unwound position. Movement of main pulley **312** from the second wound position to the first unwound position permits piston and rod assembly **32** to move from its rearward position to its forward position, due to the pressure generated by the compressed gas-charge.

Following injection, a spring (not shown) urges finger trigger linkage **350** from its rearward position to its forward position. Movement of finger trigger linkage **350** to its forward position results in movement of main trigger rod **306** from its rearward to its forward position, and movement of trigger pivot arm **328** from its unlocked position to its locked position. The user is now able to repeat the charging procedure.

Alternatively, barrel trigger **356** is urged from its rearward position to its forward position by barrel trigger spring **352**. A mechanical spring between trigger pivot arm **328** and first trigger lever **338** (not shown) pulls these parts together, thereby moving trigger pivot arm **328** from the released position to the locked position.

A trigger safety is optionally included. In this embodiment, trigger safety **304** is movable from a locked position to an unlocked position. When charging handle **300** is moved from the first closed position to the second open position, main shaft **302** rotates and causes trigger safety **304** to move from an unlocked position to a locked position. In the locked position, trigger safety **304** prevents main triggering rod **306** from moving to its rearward position. Trigger safety **304** is pivotally mounted on main gear end **308**, and has two springs (not shown) that urge trigger safety **304** to the locked position. Trigger safety **304** moves from the locked position to the unlocked position when charging handle **300** is moved to its first closed position. Ratchet mechanism **311** and pawl **313** act on trigger safety **304**, so as to enable main trigger rod **306** to move to its rearward position.

The needle-free injector depicted in Figures 11 – 21 can also be actuated using a motorized means for charging. In the case of motorized charging, charging handle **300** can remain in place or be removed. If charging handle **300** remains in place, a ratchet

mechanism (not shown) is included and permits for normal operation of injector by gear motor **360**. Additionally, if charging handle **300** is present, trigger safety **304** is deactivated using a safety deactivating cap (not shown).

In accordance with one embodiment of the present invention, gear motor **360** is a DC gear motor that is powered by a battery, such as a re-chargeable battery. Optionally, the battery is located in battery mount **358**. A user activates gear motor **360** using a rocker switch (not shown), which allows electricity from the battery to flow to gear motor **360**. Gear motor **360** rotates pinion gear **362**, which rotates crown gear **334**. Secondary shaft **332** rotates drive gear **300** (as described above), which rotates triggering gear **326**. Main gear **310** rotates main pulley **312**, which winds cable **314**, thereby moving piston and rod assembly **32** from the forward to the rearward position.

In this embodiment, the dosage ring (not shown) includes an electric limit switch (not shown), which once reached by the gap coupling **13** and piston and rod assembly **32**, interrupts the flow of electricity to gear motor **360**, thereby stopping charging. The load is held by same uni-directional clutch **336** on secondary shaft **332**, as described for manual charging.

Triggering is accomplished in the same manner as described in manual charging, using either barrel trigger **356** or finger trigger **354**.

Once piston and rod assembly **32** has returned to the forward position, a second electrical switch (not shown) is activated, which allows gear motor **360** to start and recharge the unit again.

A third electrical switch (not shown) is mounted on finger trigger **354**, which acts as a safety switch. Finger trigger **354** must be in its forward position (or released from any pushing or squeezing) for motor **360** to restart. This is to insure that triggering gear **326** and main gear **310** are engaged before the gear motor **360** starts.

Figures 22 – 25 depict a needle-free injector according to another embodiment of the present invention. The injector depicted in Figures 22 - 25 also includes a gear assembly to transfer and/or amplify an actuation force applied to the injector for moving the piston and

rod assembly against the gas charge. The gear assembly is operatively associated with either a manual means or motorized means for moving the piston and rod assembly in order to provide a mechanical advantage to facilitate charging of the actuator. The injector depicted in Figures 22 -25 further includes an actuating member operatively associated with the rod of said piston and rod assembly. Whereby, said manual means or said motorized means transfers a force to said gear assembly which transfers the force to said actuating member to move said piston and rod assembly from the forward position to the rearward position.

Referring to Figures 22 – 25, housing **1** is removably connected to reservoir **16**. Actuating device **40** is disposed within guide tube **348** in housing **1**. Union connector **502** is removably attached to guide tube **248** and acts as a gap-coupling. Piston and rod assembly **32** of actuating device **40** is removably attached to guide tube **348.** Piston **15** is slidingly disposed within reservoir **16** and is slidingly attached to union coupler **502**. Gear rack **504** is attached the outer surface of guide tube **348**, and is slidingly disposed within slot **507** of housing **1**.

As described above, movement of piston and rod assembly **32** from its forward position to its rearward position charges actuation device **40**. In the device depicted in Figures 22 to 24, charging of the injector is achieved by moving gear rack **504** from a forward position to a rearward position, which in turn moves piston and rod assembly **32** from its forward to its rearward position. Accordingly, gear rack **504** is serving as an actuating member.

In accordance with one embodiment of the present invention, gear motor **360** rotates pinion gear **362**, which rotates crown gear **334**. Crown gear **334** is attached to a first end of shaft **506** and gear **508** is attached to a second end of shaft **506**; gear **508** rotates as crown gear **334** rotates. Shaft **506** is mounted in gear mount **509**, which is attached to housing **1**.

Gear **508** rotates idler gear **510**, which rotates compound gear **512**. Compound gear **512** includes outer gear **514** and inner gear **516**. Idler gear **510** rotationally engages outer gear **514**. Inner gear **516** rotationally engages charging gear **520**. Rotation of compound gear **512** rotates charging gear **520**.

Charging gear **520** includes first gear **518** and recessed second gear (not shown, but generally indicated by the line denoted by numeral **522**). Charging gear **520** is rotationally attached to clutch mount **540;** clutch mount **540** is pivotally attached to housing **1** at attachment mount **542.** Charging gear **520** is movable between an charging position and a release position. In the charging position, first gear **518** of charging gear **520** engages gear rack **504** and is operable to move gear rack **504** from its forward to its rearward position, thereby moving piston and rod assembly **32** against the gas charge from the forward to rearward position, to charge actuating device **40**. Recessed second gear **522** rotationally engages locking gear **524**, which is attached to uni-direction clutch **336.**

Uni-directional clutch **336** and locking gear **524** enable charging gear **520** to rotate when moving gear rack **504** from its forward position to its rearward position, and does not allow charging gear **520** to rotate so as to move gear rack **504** from its rearward to its forward position. Thus, uni-directional clutch **336** holds the charge of actuating device **40**.

Charging of actuating device **40** continues until the desired charge is achieved. In one example, dosage ring **526** is used to set the desired charge. In this example, dosage ring **526** is positioned on housing **1** at a user determined position, and can be locked into place. Dosage ring **526** includes guide **528** for receiving gear rack **504**. Guide **528** includes gearing teeth (not shown) on the inner surface that matingly engage with gear rack **504**. When dosage ring **526** is locked on housing **1** and gear rack **504**, the extent to which gear rack **504** and piston and rod assembly **32** can be drawn back is user determined; therefore, the dosage ring is user adjustable to set the amount of medicament that is ultimately drawn in to the injector, for subsequent injection. The dosage ring may be set to include a wide range of charges, and thus injection volumes. In one example, the dosage ring is adjustable over a range of volumes between about 0.01cc to about 5cc.

When charging gear **520** is moved from its charging position to its release position, charging gear **520** disengages gear rack **504**, permitting gear rack **504** to move from its rear ward position to its forward position.

In this example, the trigger is a trigger mechanism that releasably retains piston and rod assembly **32** in its rearward position.

Charging gear **520** is operably connected to barrel trigger **356** or finger trigger **354** by trigger release **532**. Trigger release **532** is attached to clutch mount **540** and is operable to move charging gear **520** between its charging position and its release position. In the example of Figure **22** – **24**, dosage ring **526** includes trigger catch **530**, which is configured to releasably engage trigger release **532**. When gear rack **504** has been moved to its rearward position, trigger catch **530** engages trigger release **532**. Following attachment of trigger catch **530** to trigger release **532**, charging gear **520** is moved from its charging position to its release position. Accordingly, the charge within actuation device **40** is held in place by the attachment of trigger catch **530** to trigger release **532**.

Actuatation of the needle free injector is accomplished using barrel trigger **356** or finger trigger **354**. In each instance, actuation is achieved by moving trigger release **532** to disengage trigger catch **530** from trigger release **532**, thereby permitting gear rack **504** to move from its rearward position to its forward position. Using finger trigger **354**, depressing finger trigger **354** causes disengagement of trigger catch **530** from trigger release **532**. Using barrel trigger **356**, nozzle **17** is pushed onto the body to be injected with enough force to move barrel trigger **356** against a barrel spring (not shown) so as to cause disengagement of trigger catch **530** from trigger release **532**.

In an alternative embodiment, the needle free injector depicted in Figures 22 – 24 is adapted for manual charging. In the case of manual charging, gear motor **360** is not used. Instead, a charging handle and ratchet mechanism (not shown) directly or indirectly rotate gear **506**. In the case of indirect rotation of gear **506**, a chain gear is optionally used to connect the charging handle and ratchet mechanism to gear **506**. Charging and actuation is carried out as described above.

It will be clear to the skilled worker that various arrangement of gears and gearing can be used in a gear assembly to increase the mechanical advantage for charging actuating device **40**. For example, a "gear train" consisting of several gears acting on each other can drive a rack and pinion, which acts directly or indirectly on piston and rod assembly **32** to move piston and rod assembly to its rearward position. A planetary drive gear box can be used to act on the directly or indirectly on piston and rod assembly **32**, in a similar fashion.

Similarly, a planetary gear box and ratchet system may be used. The use of a worm gear drive is another alternative. Any combination of or set up of any suitable individual "gear option" can increase the mechanical advantage several times, thereby reducing the force charge actuating device **40**. The addition and use of such "gear trains" makes it easier for users to charge actuating device **40**.

As would be readily appreciated by a worker skilled in the art, the positioning of the nozzle against the subject will depend on a number of factors, including, but not limited to, the species and body region to be injected, the age of the subject to be injected, and the pressure of the gas charge. For example, certain animal species will have skin that is more difficult to pierce than others. This is due, in part, to species differences in skin thickness. Additionally, members of a particular species will have regions of the body that are more or less difficult to inject. The age of the animal and or human may also have an effect on the ease of injection, since skin thickness and coarseness can vary with age. For example, in some species, a younger individual (e.g., neonate or infant) will have skin that is more readily injectable than an adult individual. As well, in a variety of animals, for example, regions behind the ears or in creases of limbs will typically be easier to inject. Those body regions that are more readily injected will require a lower pressure gas charge compared to a body region that is more difficult to inject. The skilled worker will appreciate and take into consideration the various species, body region and/or age differences, when selecting the pressure of the gas-charge.

The injection device of the present invention optionally includes a supply reservoir for supplying liquid to dosing reservoir **16**. In a specific, non-limiting example, as depicted in Figure 2 and 9, supply reservoir is syringe **21** containing a medicament. In Figure 8 the supply reservoir is bottle **208** containing a medicament. Syringe **21** and bottle **208** are connected to dosing reservoir **16** by a length of tubing **19** and a one-way valve **18**. One-way valve **18** allows unidirectional movement of medicament from syringe **24** to dosing reservoir **16**. In these embodiments movement of plunger **15** from the forward position to the rearward position in dosing reservoir **16** causes a single dose of medicament to be drawn from syringe **21** into dosing reservoir **16**.

In accordance with another aspect of the present invention there is provided a method of using the needle-free injection device for injection of a liquid through the skin of a subject, that may be an animal or human. The method comprises the steps of (i) providing a needle-free injection device of the present invention having at least one dose of the liquid to be administered; (ii) actuating the device by moving piston and rod assembly **32** to the rearward position; placing nozzle **17** against the skin of the subject to be injected; and (iii) triggering the actuation device to expel a dose of the liquid through the outlet orifice and nozzle **17** and through the skin of the subject.

All publications, patents and patent application mentioned in this Specification are indicative of the level of skill of those skilled in the art to which this invention pertains and are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

The invention being thus described, it will be obvious that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the invention, and all such modifications as would be obvious to one skilled in the art are intended to be included within the scope of the following claims.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. In a needle-free injection device for delivering a medicament under pressure from a dosing reservoir through an outlet orifice for administration to an animal or human, of the type comprising a plunger slidably received in said dosing reservoir and movable in a forward direction for expelling said medicament through said orifice, characterized in that said injection device comprises an actuating device comprising:

   (a) a gas tight chamber;

   (b) a piston and rod assembly slidably received in said chamber and movable between a forward position and a rearward position;

   (c) a gas charge in said chamber for urging said piston and rod assembly to said forward position;

   (d) means for moving said piston and rod assembly against said gas charge into said rearward position; and

   (e) a trigger for releasably retaining said piston and rod assembly in said rearward position,

   whereby activating said trigger causes said piston and rod assembly to be released for movement by said gas charge to said forward position so as to impact said plunger directly or indirectly with a force sufficient to cause said plunger to move in said forward direction to expel said medicament through said outlet and whereby said gas tight chamber is adapted to minimize or prevent the escape of said gas charge so as to maintain said gas charge in a pressurized state.

2. The needle-free injection device according to claim 1, wherein the circumference of the piston of said piston and rod assembly defines an outer edge that is in contact with the interior surface of said gas tight chamber such that the piston defines an extension portion and a compression portion of said gas tight chamber.

3. The needle-free injection device according to claim 2, wherein said piston of said piston and rod assembly comprises a passage for fluid communication between said extension portion and said compression portion of the gas tight chamber.

4. The needle-free injection device according to any one of claims 1 to 3, wherein said gas charge is a compressed inert gas or a mixture of compressed inert gas.

5. The needle-free injection device of claim 4, wherein the compressed inert gas is nitrogen.

6. The needle-free injection device according to any one of claims 1 to 5 further comprising a lubrication medium for lubricating said piston and rod assembly

7. The needle-free injection device according to claim 6, wherein lubrication medium is a light weight oil.

8. The needle-free injection device according to any one of claims 1 to 7 further comprising a gap-coupling connecting the rod of said piston and rod assembly to the plunger, wherein said gap-coupling is configured to maintain a gap-distance between said rod and said plunger when said piston and rod assembly is in said rearward position.

9. The needle-free injection device of claim 8 wherein the gap-coupling comprises:

(a) a first end for removable attachment of the gap-coupling to said rod; and

(b) a second end for sliding engagement with the plunger.

10. The needle-free injection device according to any one of claims 1 to 7 further comprising means for transferring force generated by movement of said piston and rod assembly to said plunger, whereby activating said trigger causes said piston and rod assembly to be released for movement by said gas charge to said forward position thereby imparting a force to said means for transferring force which in turn imparts the force to said plunger sufficient to cause said plunger to move in said forward direction to expel said medicament through said outlet

11. The needle-free injection device according to claim 1, wherein said means for moving said piston and rod assembly is a manual means.

12. The needle-free injection device according to claim 11, wherein said manual means comprises:

(a) a handle pivotally connected to said needle-free injection device and pivotable from a first closed position to a second open position;

(b) a push rod pivotally attached to said handle; and

(c) an actuating member operatively associated with the rod of said piston and rod assembly,

whereby when said handle is moved from said first closed position to said second open position said push rod engages said actuating member and when said handle is returned to said closed position a pushing force is transferred to said push rod, which in turn transfers the pushing force to said actuating member to move said piston and rod assembly from said forward position to said rearward position.

13. The needle-free injection device of claim 1, wherein said means for moving said piston and rod assembly is a motorized means.

14. The needle-free injection device according to claim 13 further comprising:

(a) a gear assembly operatively associated with said motorized means; and

(b) an actuating member operatively associated with the rod of said piston and rod assembly,

whereby said motorized means transfers a force to said gear assembly which transfers the force to said actuating member to move said piston and rod assembly from said forward position to said rearward position.

15. The needle-free injection device of claim 13 or 14 wherein said motorized means is a DC power supply.

16. The needle-free injection device of claim 13 or 14 wherein said motorized means is an AC power supply.

17. The needle-free injection device according to claim 12, wherein the push rod is adjustable in length.

18. The needle-free injection device according to claim 12, wherein said trigger comprises a triggering lever having a first end and a second end and being pivotable about a pivot member and connected at said first end to said push rod, whereby when a downward force is exerted on said second end of said triggering lever it pivots about said pivot member and said first end is raised causing said push rod to disengage said actuating member such that said piston and rod assembly moves from said rearward position to said forward position.

19. The needle-free injection device according to claim 11, wherein said manual means comprises:

(a) a handle pivotally connected to said needle-free injection device and pivotable from a first closed position to a second open position;

(b) a gear assembly operatively associated with said handle; and

(c) an actuating member operatively associated with the rod of said piston and rod assembly,

whereby when said handle is moved from said first closed position to said second open position said gear assembly transfers a force to said actuating member to move said piston and rod assembly from said forward position to said rearward position.

20. The needle-free injection device according to claim 19, wherein said trigger comprises a trigger mechanism, whereby user activation of said trigger mechanism causes said gear assembly to disengage said actuating member such that said piston and rod assembly moves from said rearward position to said forward position.

21. Use of the needle-free injection device according to any one of claims 1 to 20, to manufacture a kit for administering a medicament to an animal or human.

22. A kit for the use of the needle-free injection device according to any one of claims 1 to 21, comprising:

(a) the needle-free injection device; and

(b) instructions for the use thereof.

23. Use of the needle-free injection device of any one of claims 1-20 for administering a medicament to a subject.

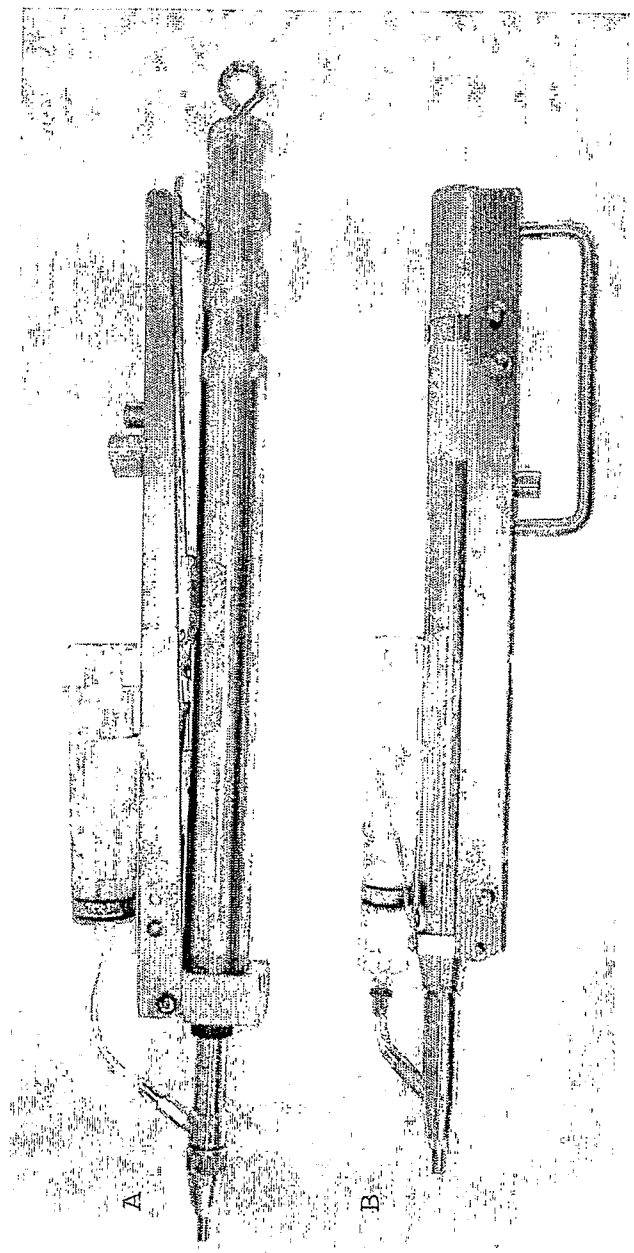


Figure 1

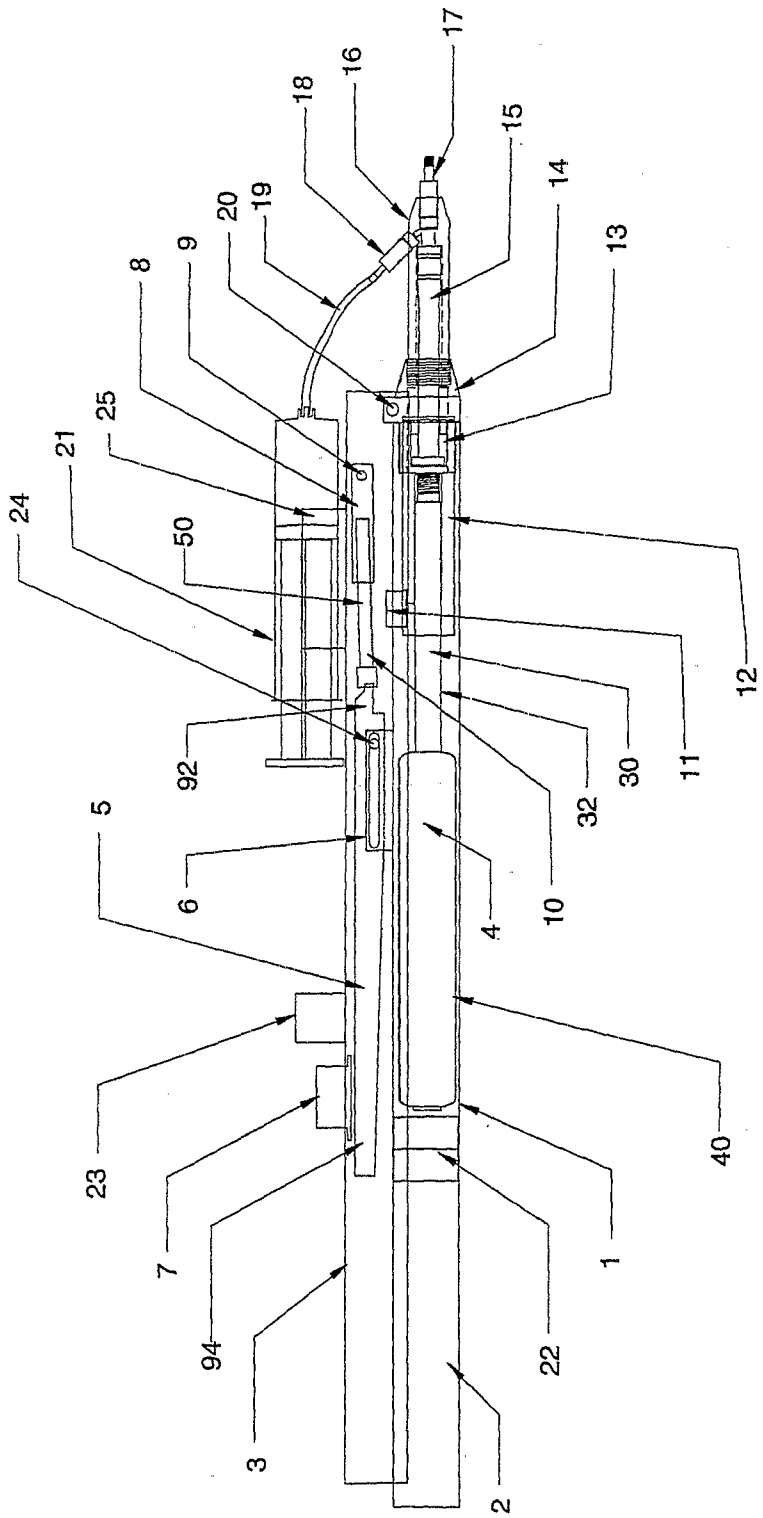
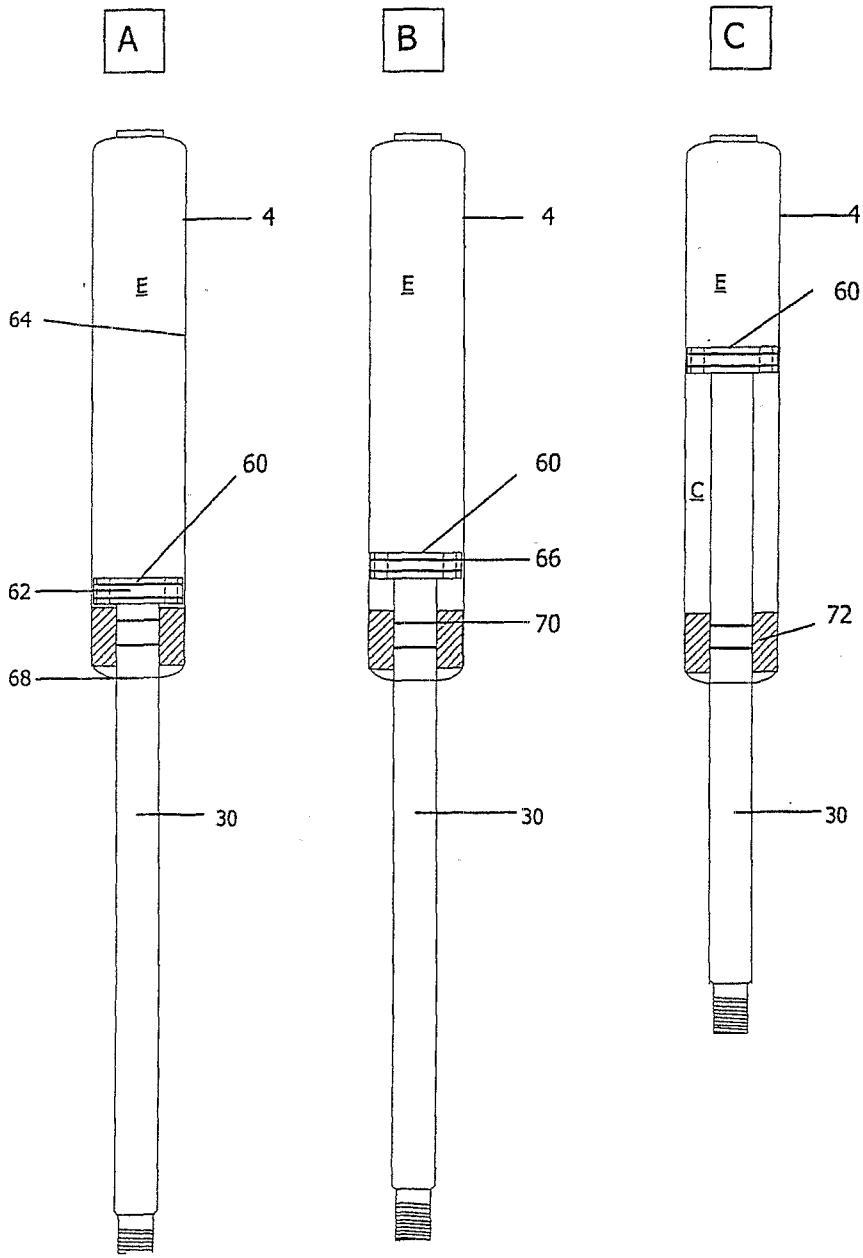

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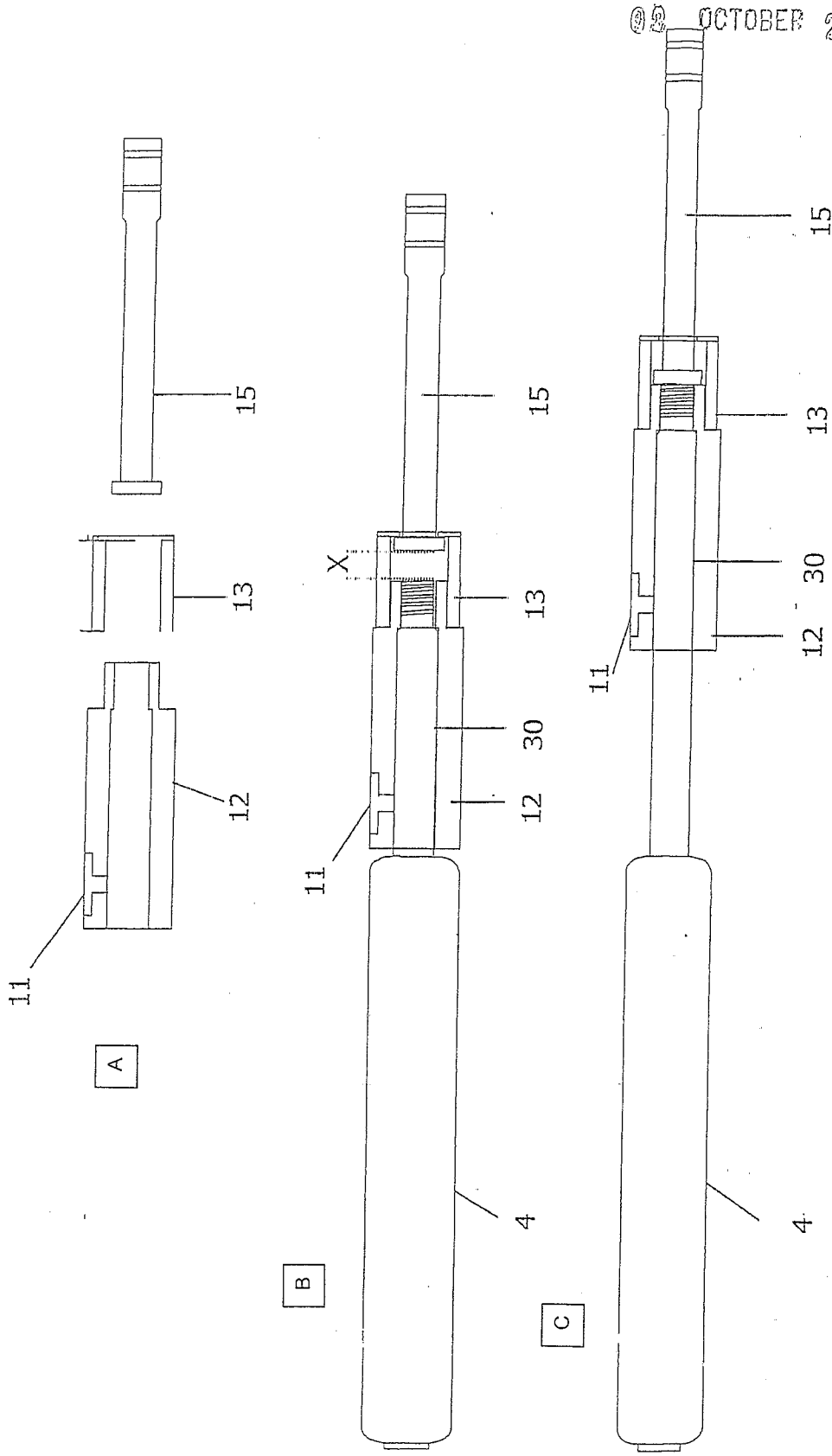
Figure 2

Figure 3



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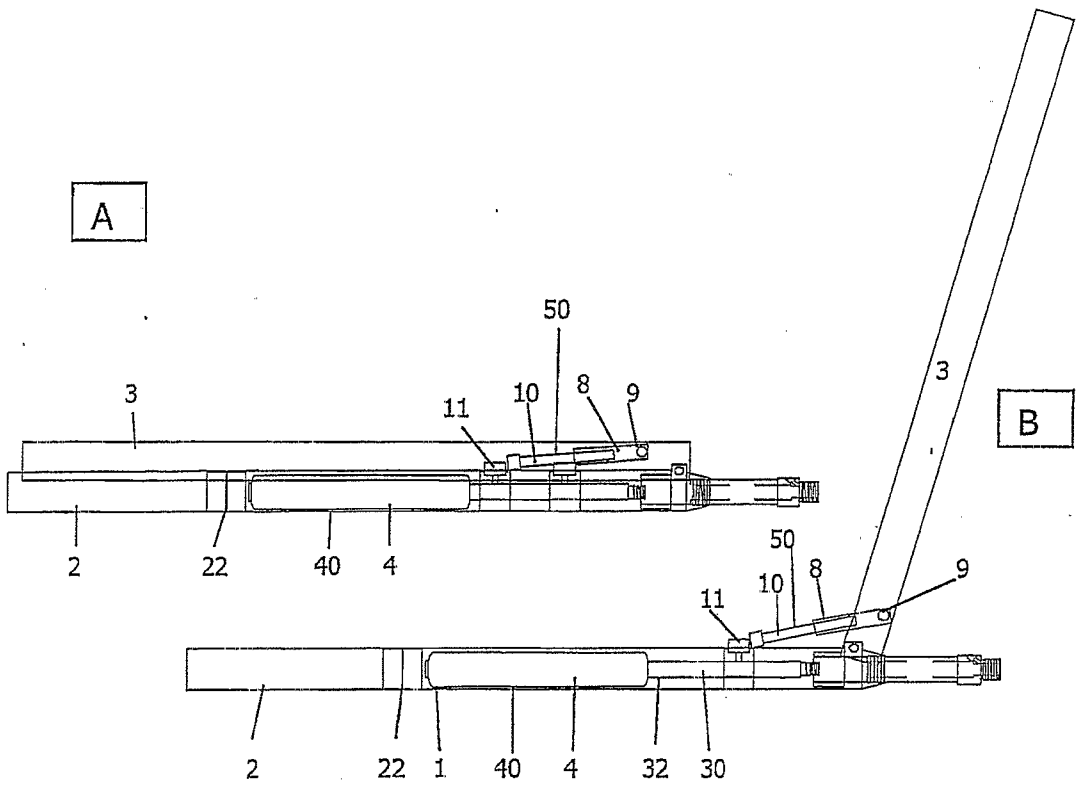
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Figure 5



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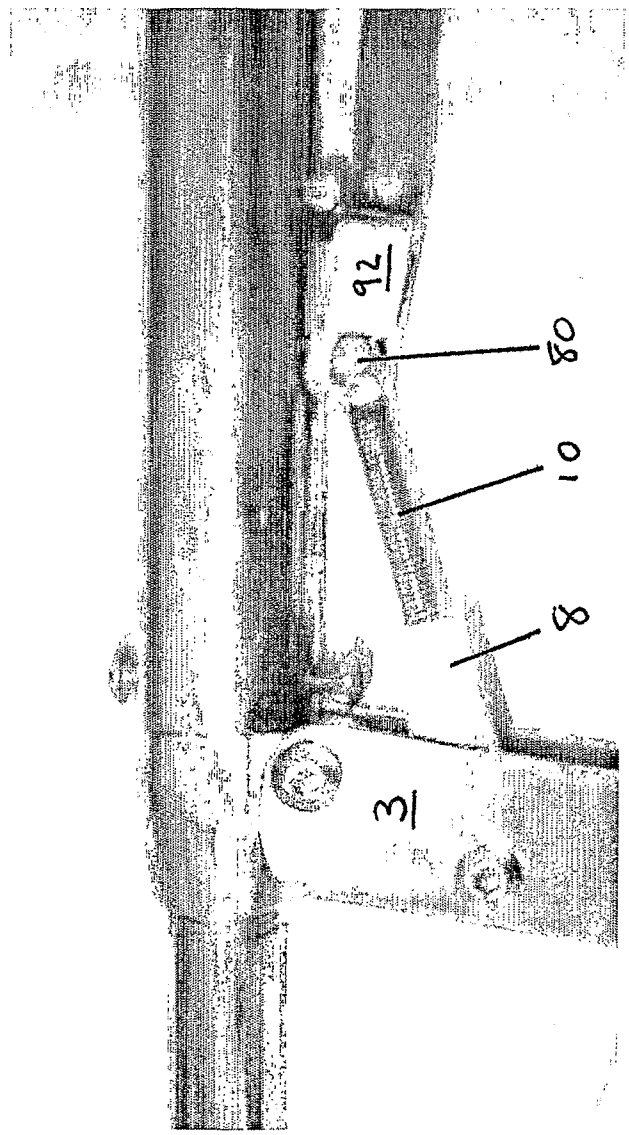
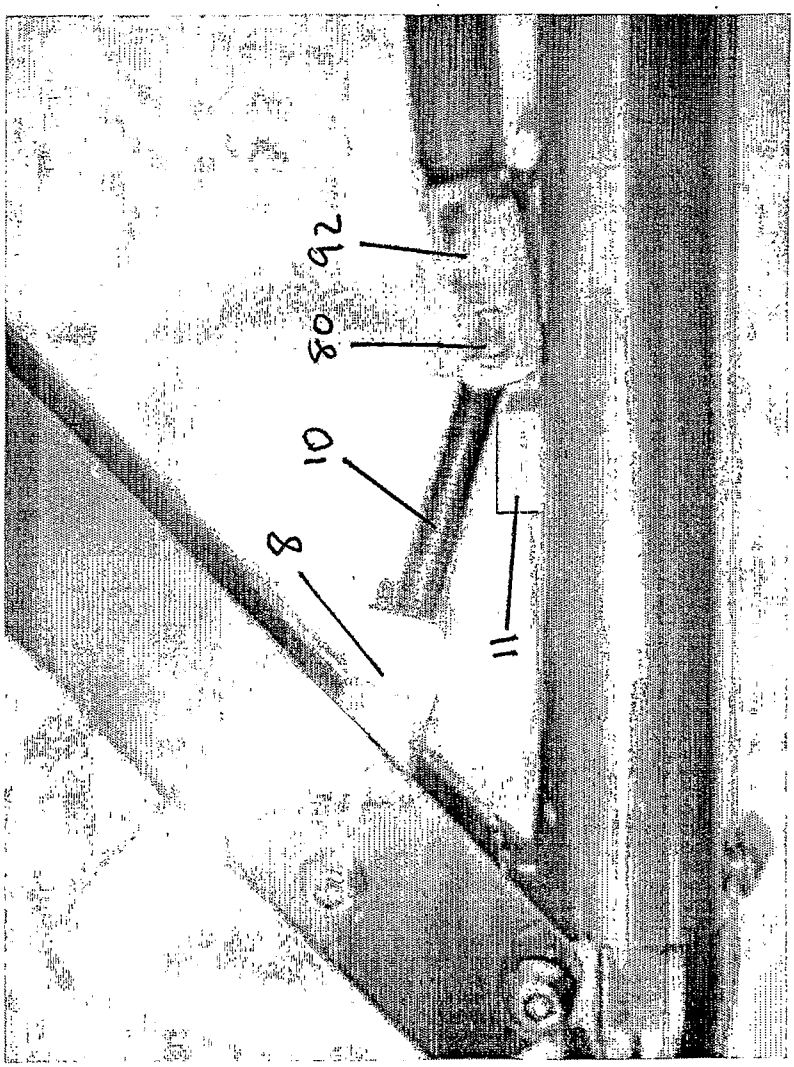


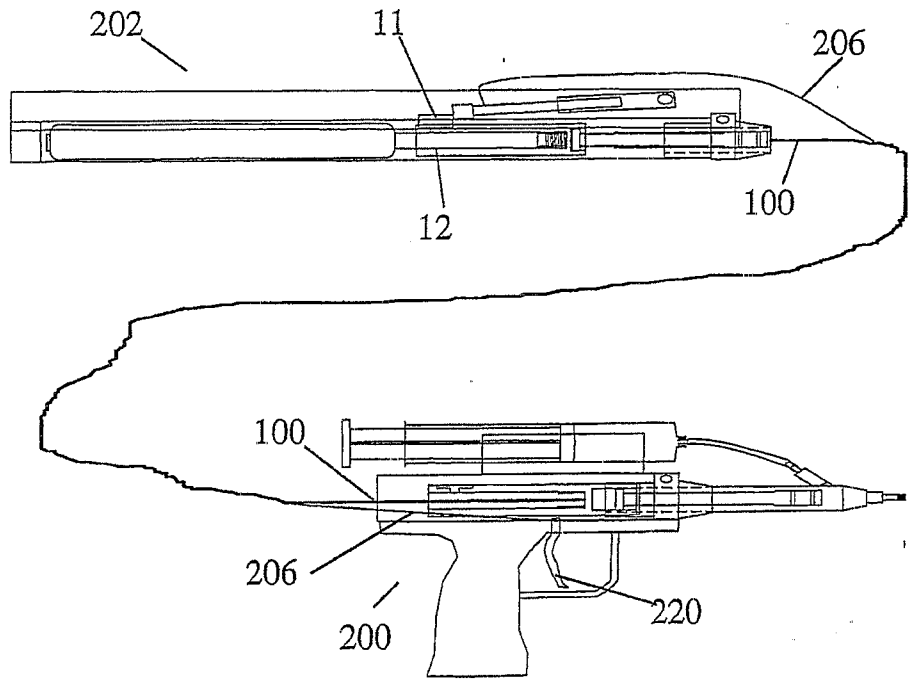
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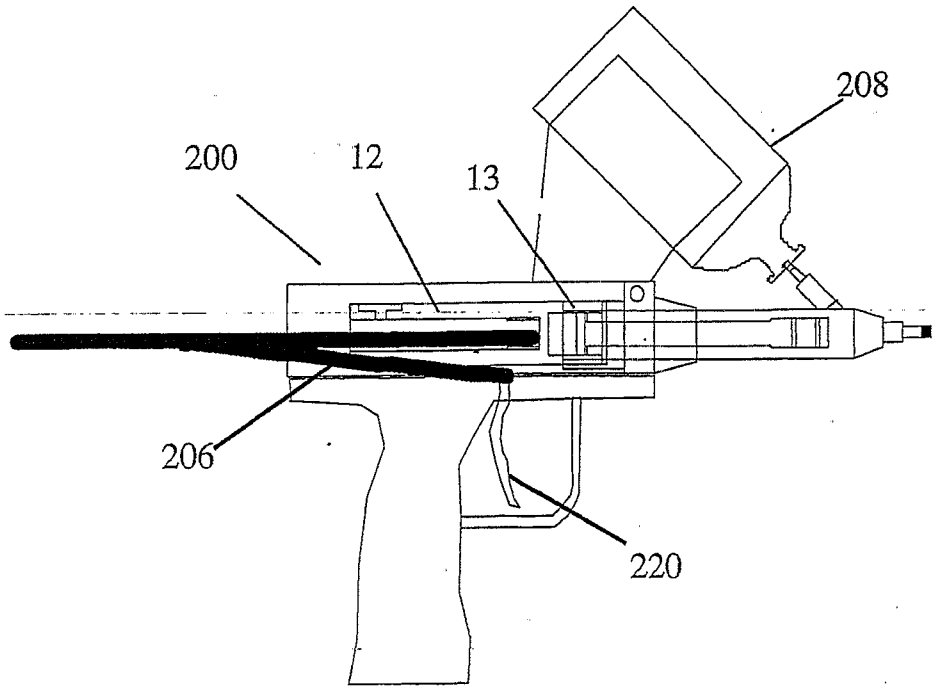
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Figure 8





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Figure 9

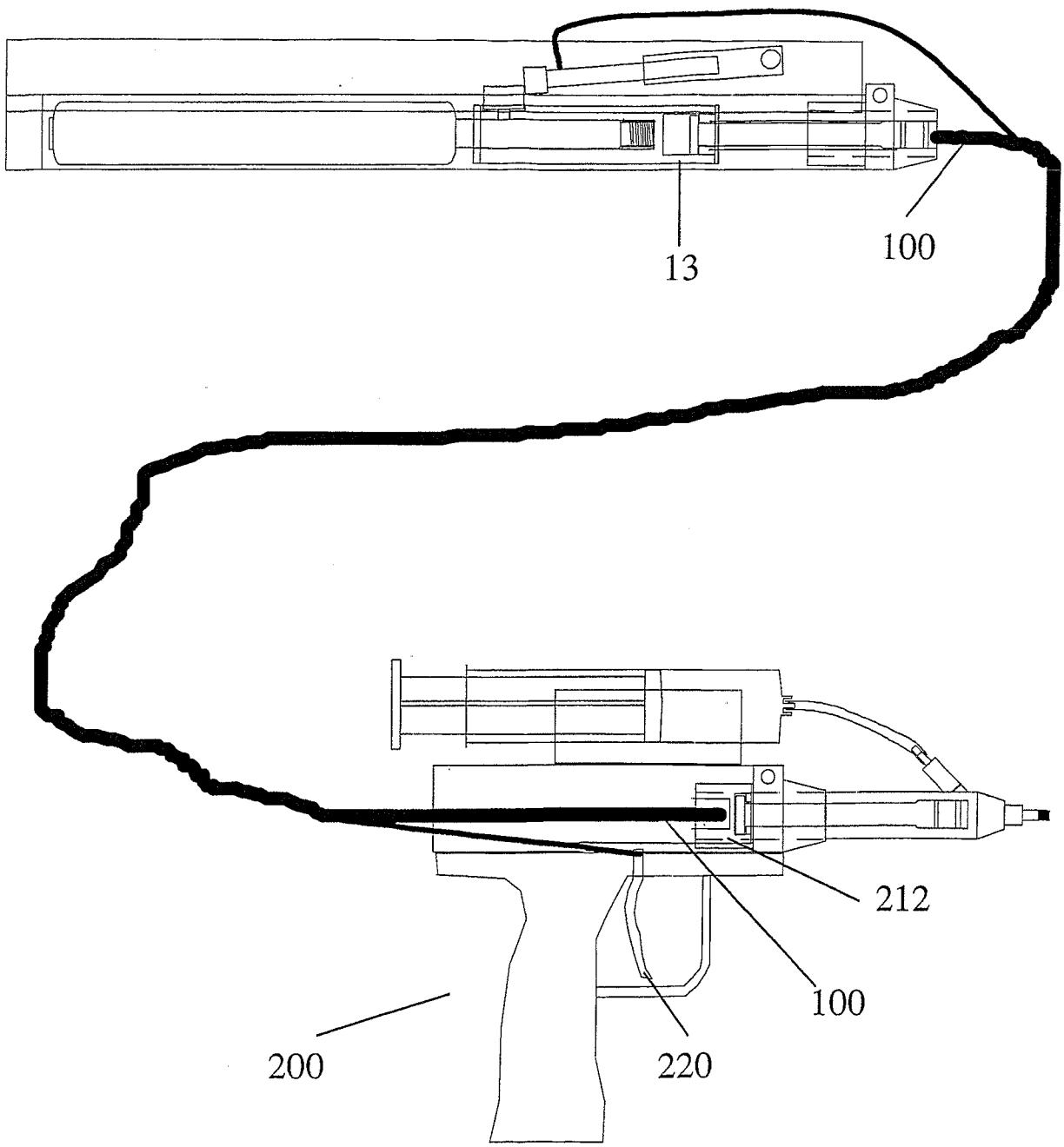
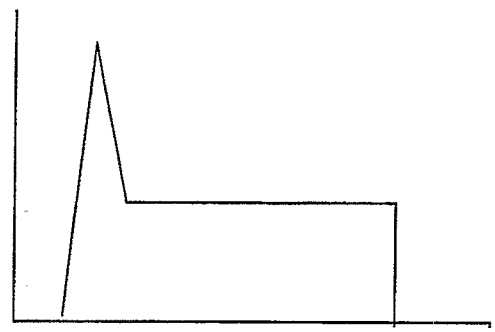


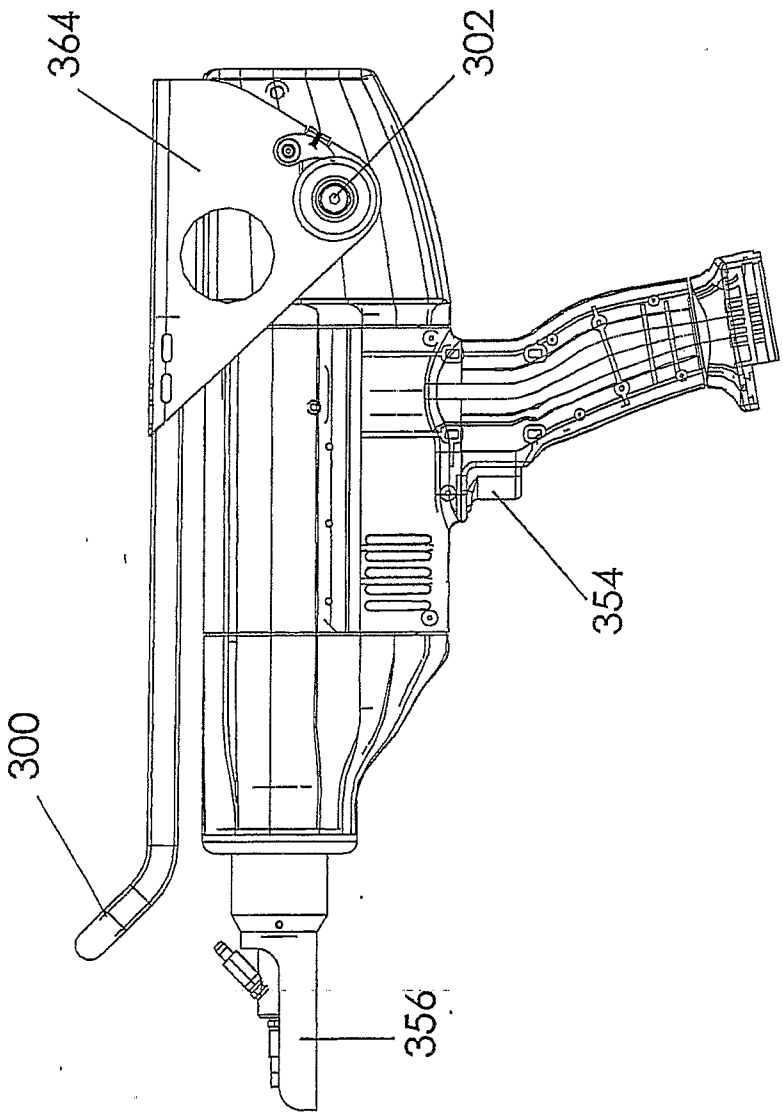
Figure 10



Pressure pattern of inventive device

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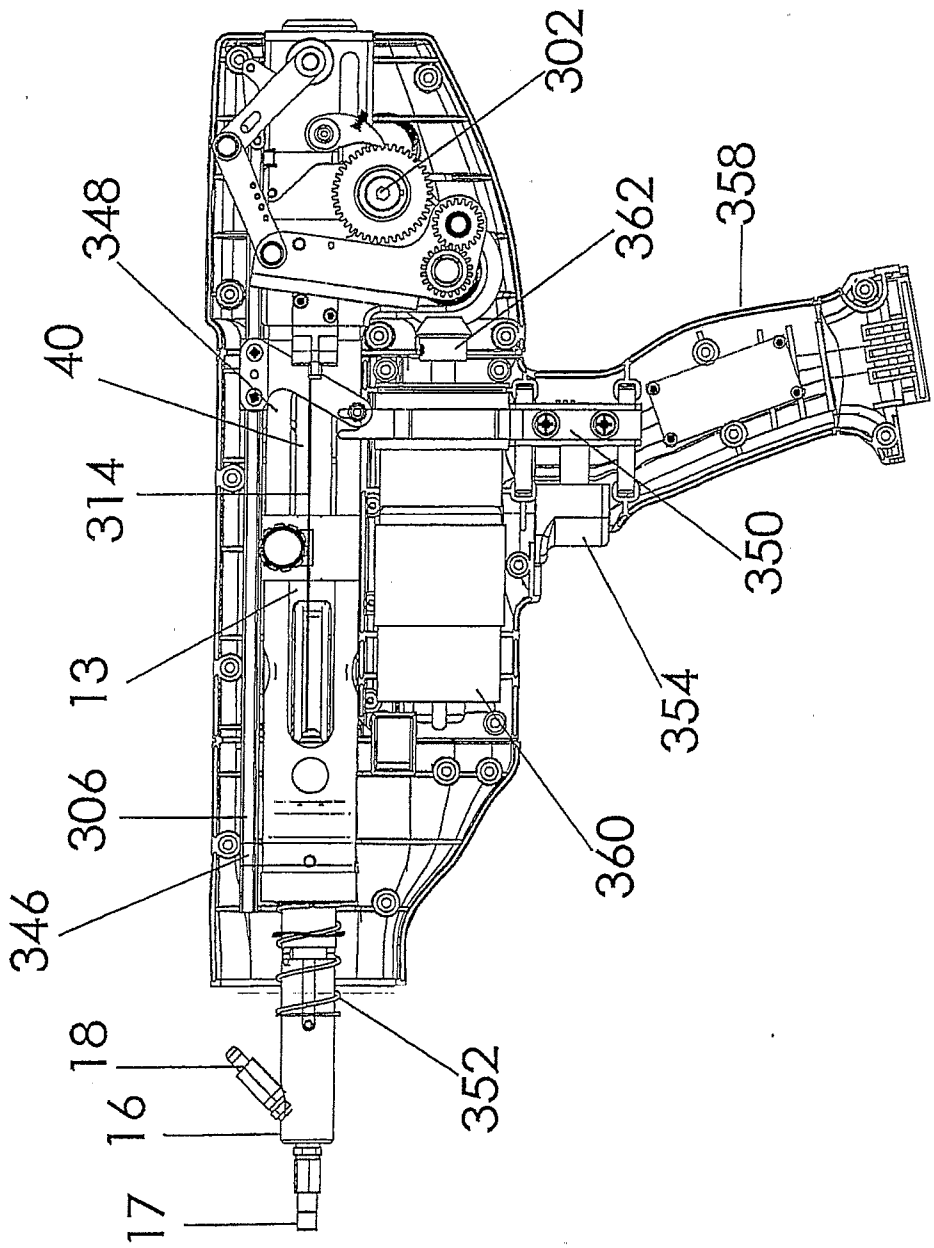
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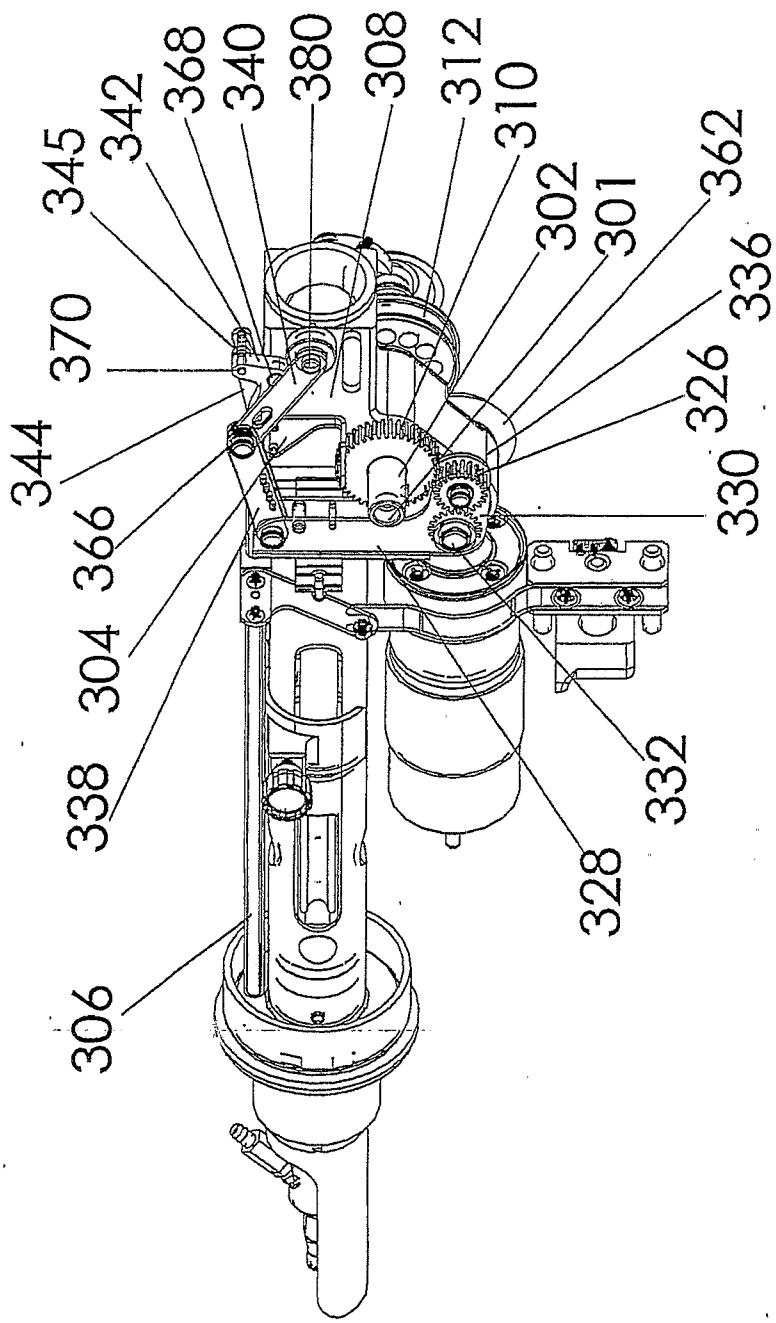
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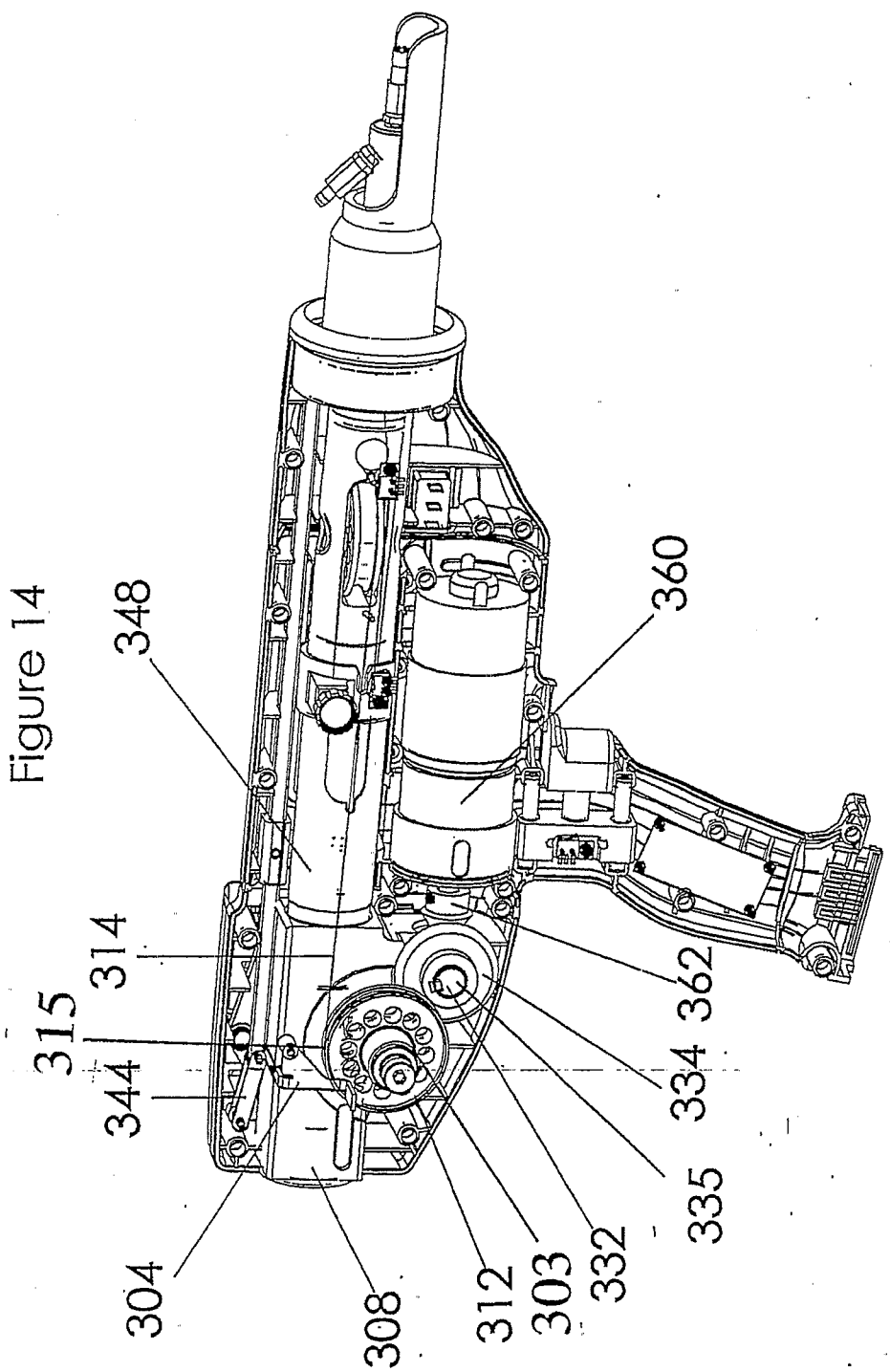
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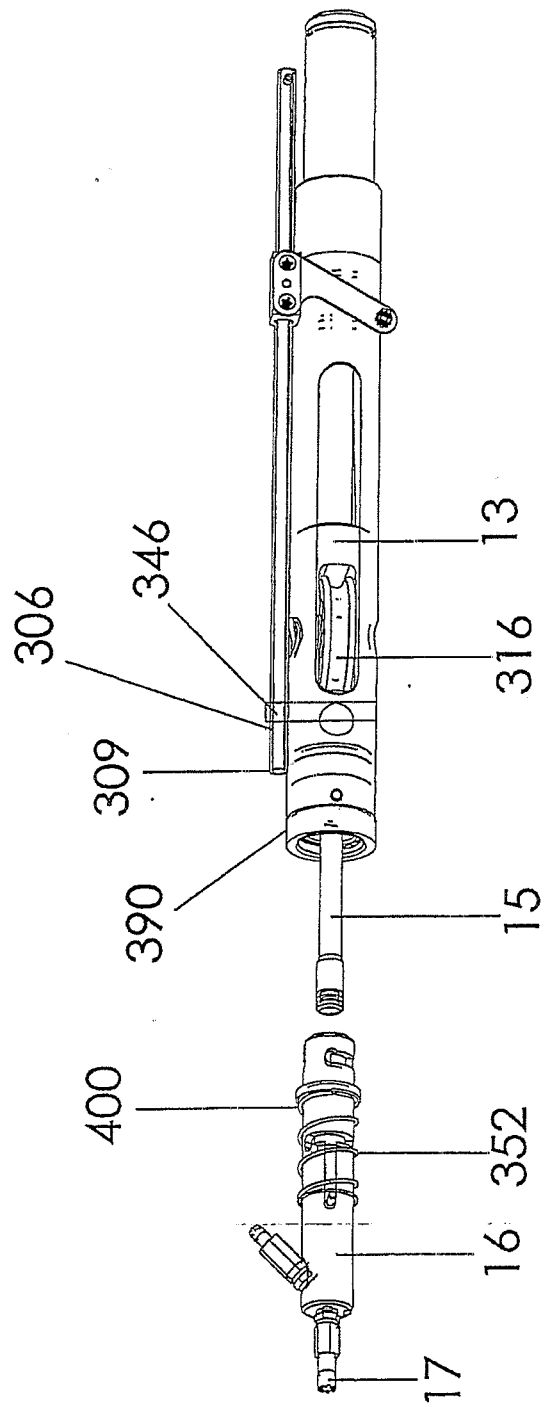
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Figure 15

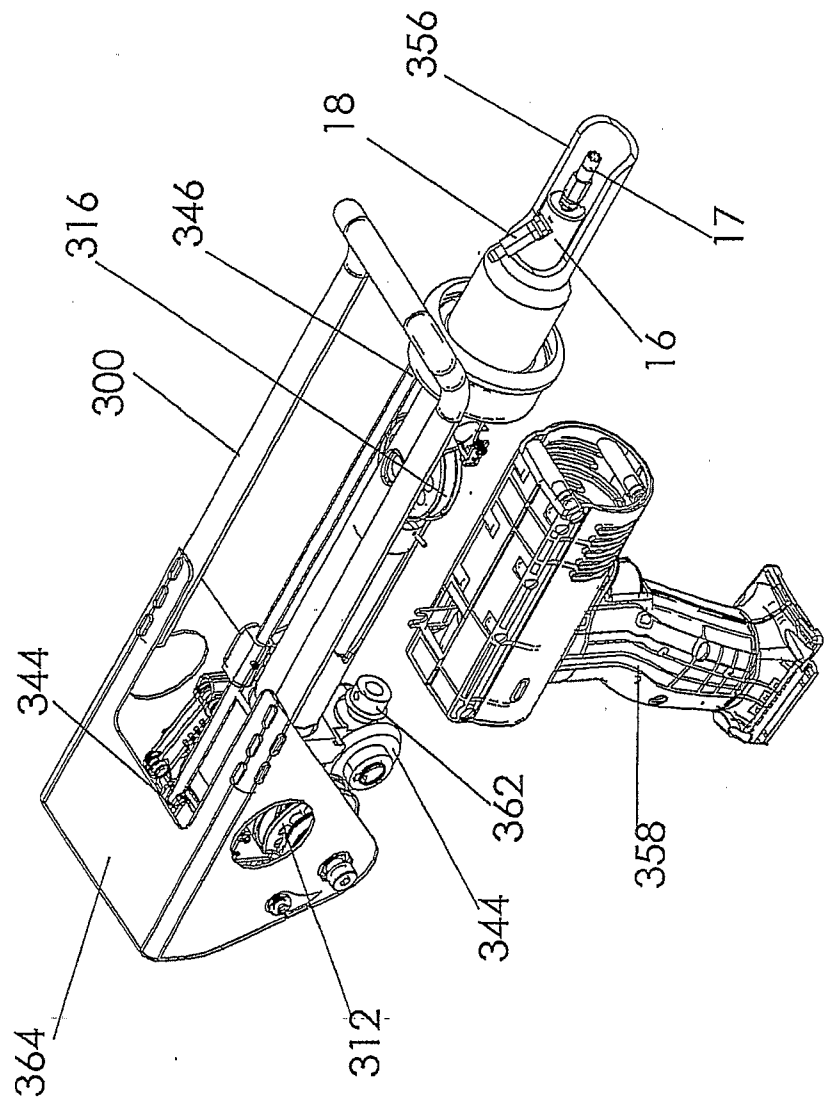


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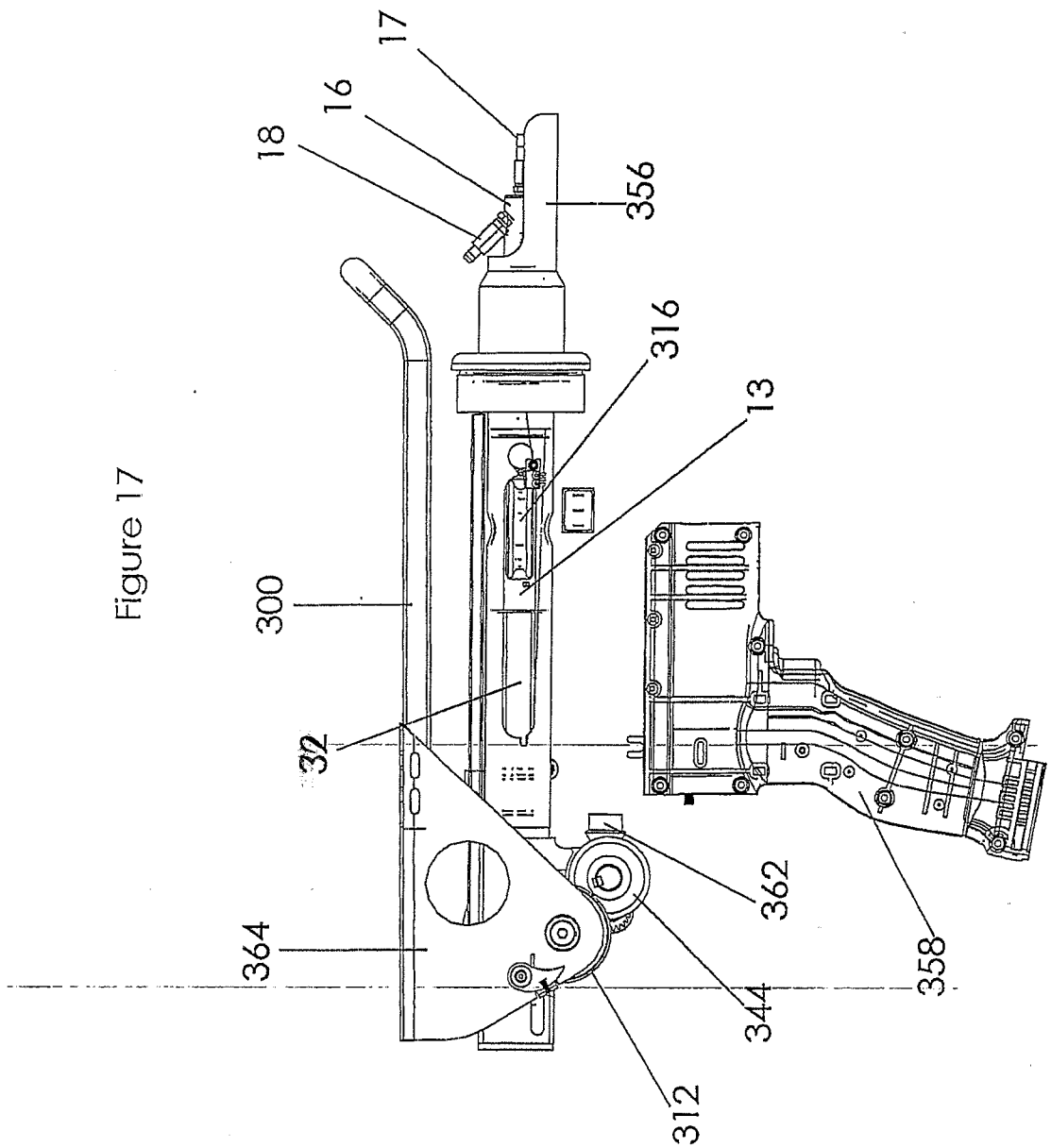
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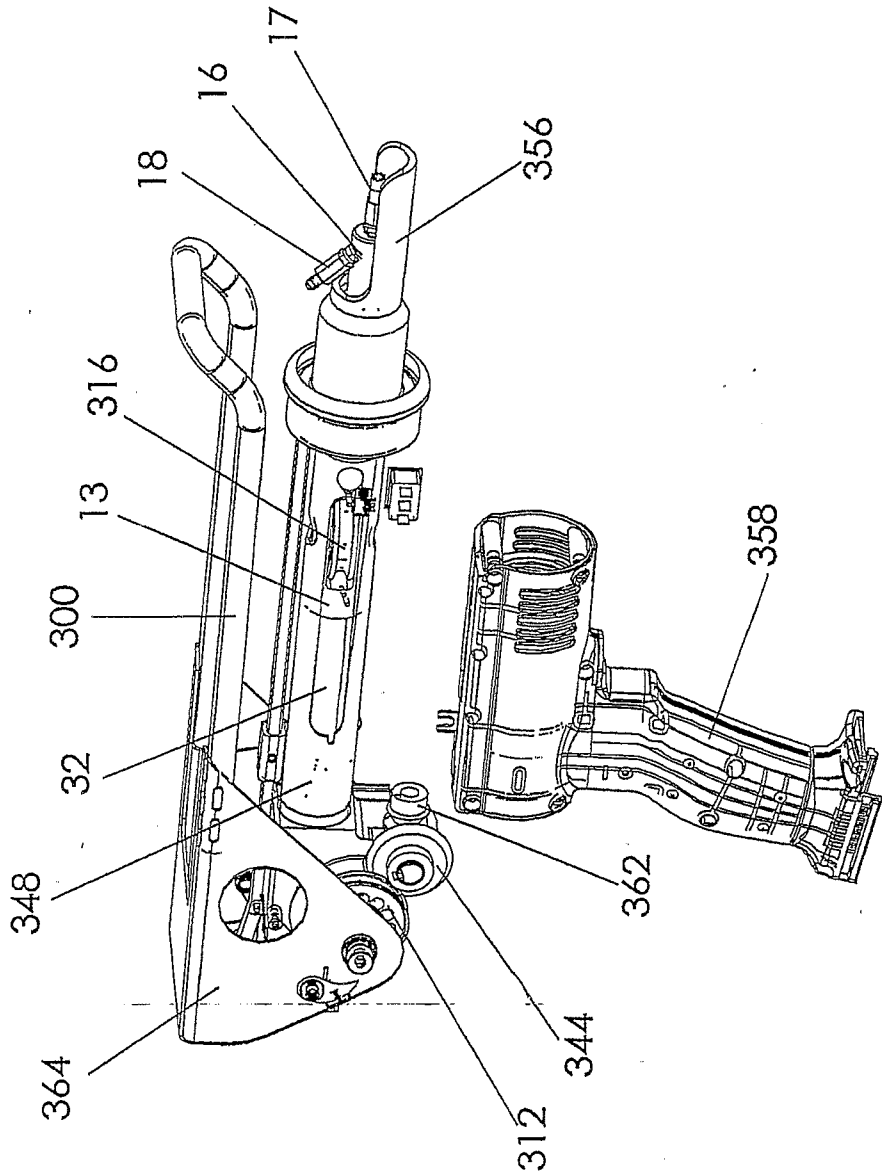
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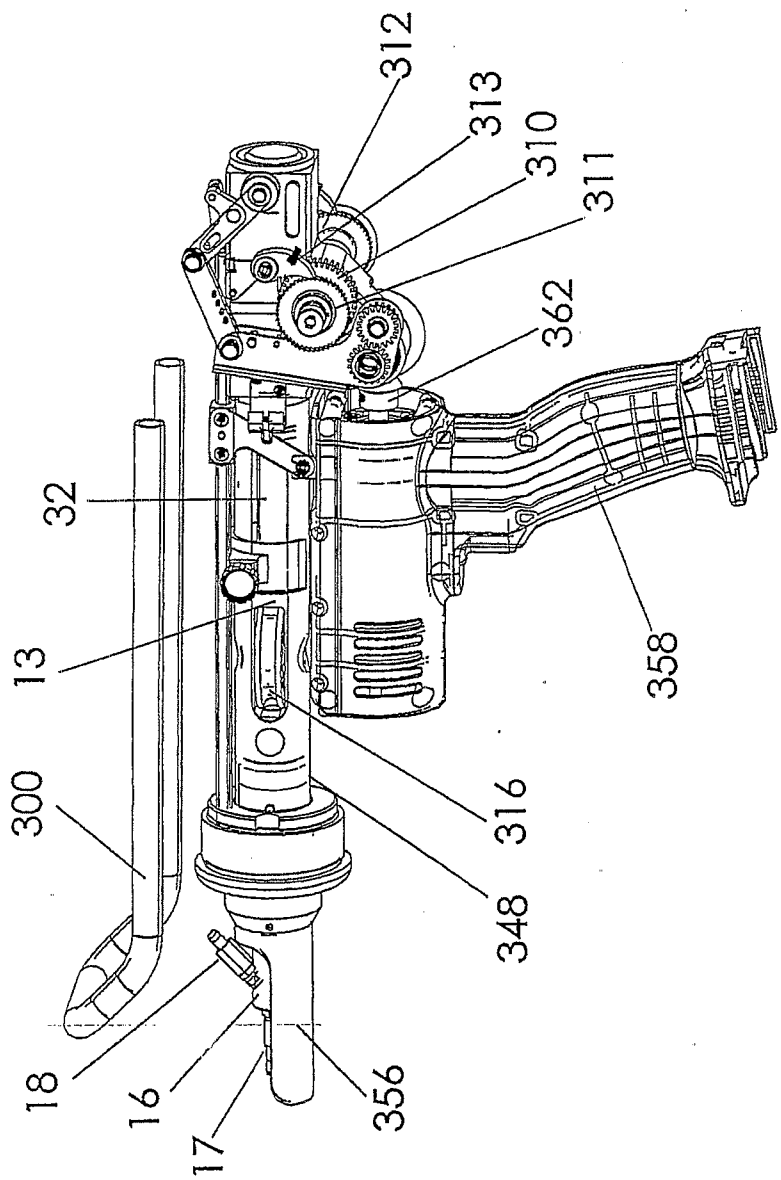
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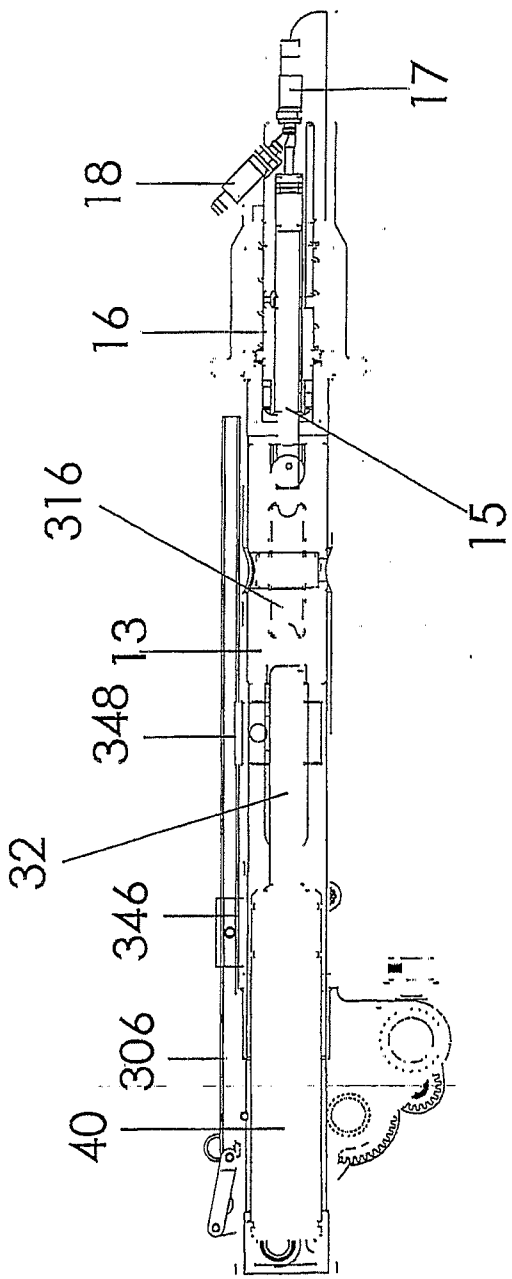
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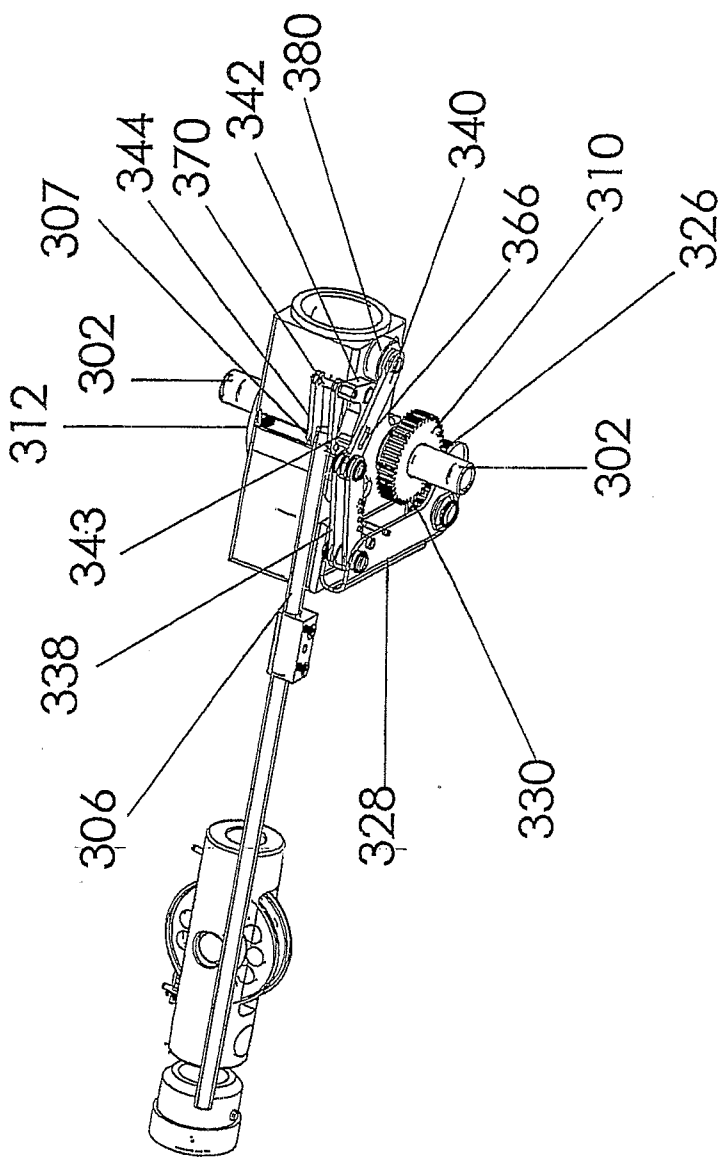
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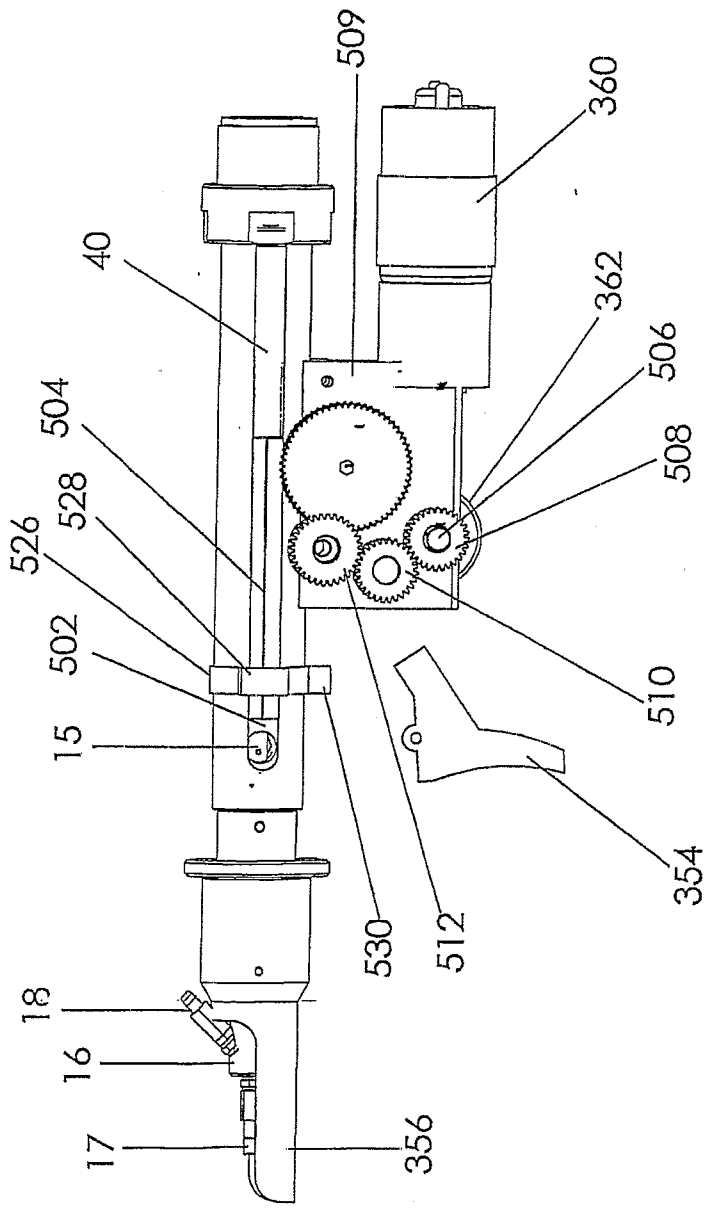
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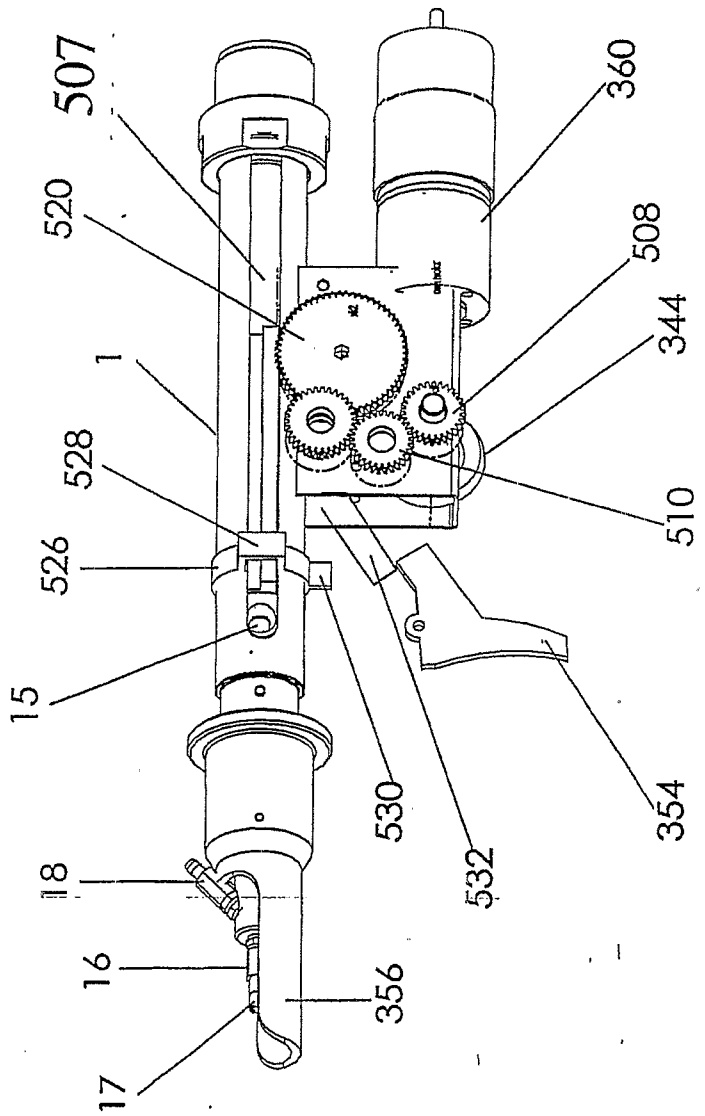
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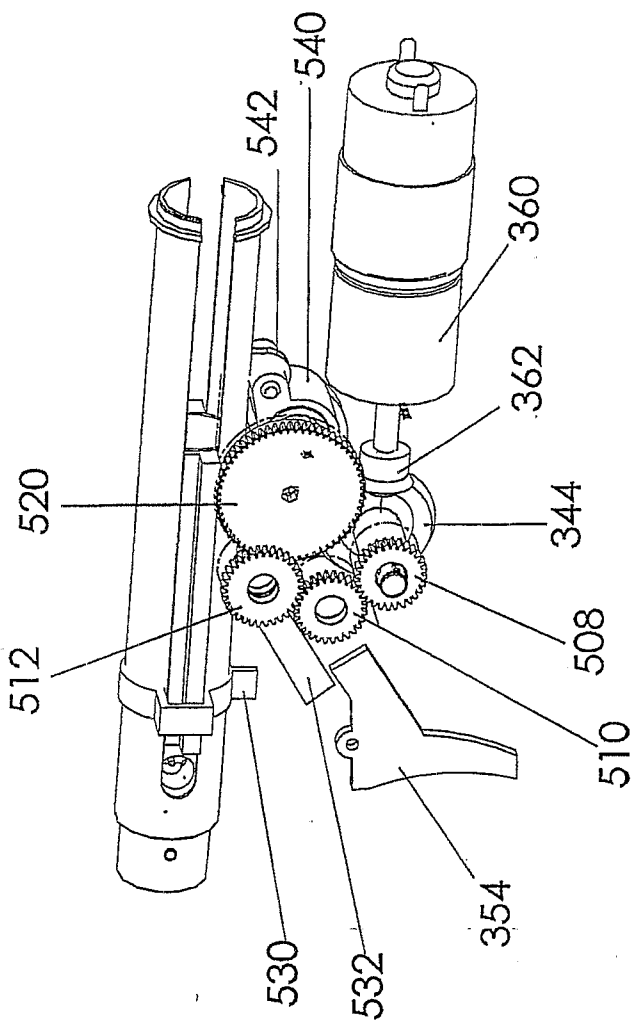
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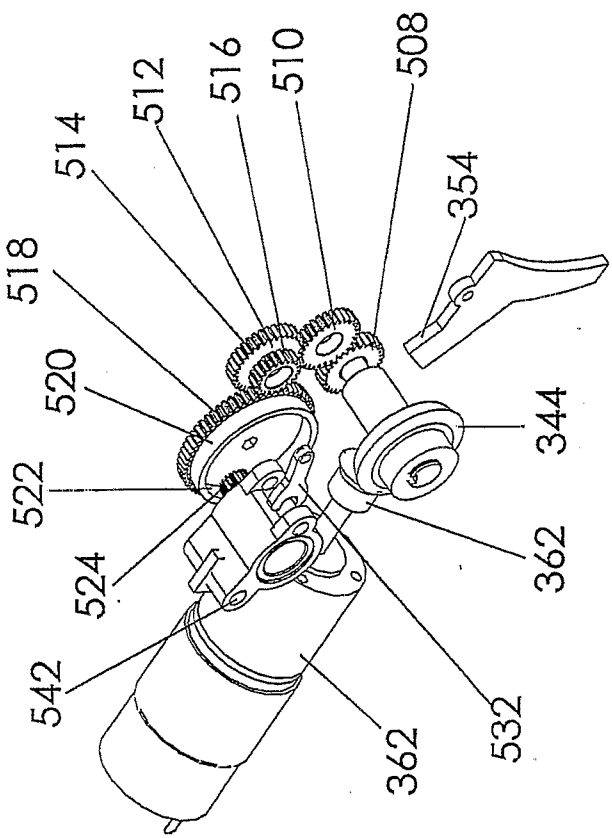


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Figure 25



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