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(54) **HAND-PIECE FOR INJECTION DEVICE WITH A RETRACTABLE AND ROTATING NEEDLE**

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(73) **Assignee:** **Milestone Scientific, Inc.**

(\*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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**Related U.S. Application Data**

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(51) **Int. Cl.<sup>7</sup>** ..... **A61M 5/00; A61M 5/32; A61M 1/00; A61M 25/00**

(52) **U.S. Cl.** ..... **604/188; 604/198; 604/151; 604/523**

(58) **Field of Search** ..... **604/110, 171, 604/192, 195, 197, 198, 263, 181, 187, 188, 164.01, 164.08, 164.12, 523, 533, 151; 128/919**

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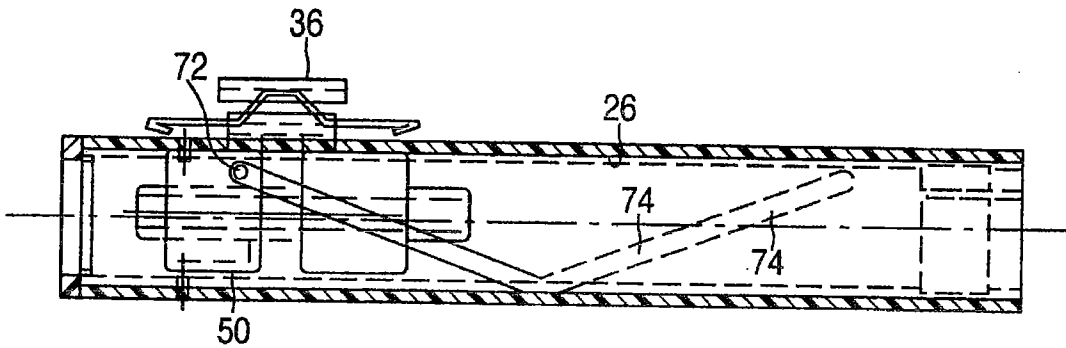
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(57) **ABSTRACT**

An injection device is arranged and constructed to simultaneously rotate a needle during its forward translation as a therapeutic agent such as a liquid is ejected therefrom. In one embodiment the injection device is an automatic device including a pump forcing the liquid through a tube to a hand-piece. The needle has a first position in which it is disposed within a housing of the hand-piece, and a second position in which the needle extends outwardly of the hand-piece so that it can be used to eject the liquid, with the needle being automatically uni- or bi-directionally rotated as it is advanced between the first and second positions. In an alternate positions a syringe is provided with a barrel, a plunger extending into the barrel to eject the liquid through the needle, and a plunger which is pushed into the barrel by the operator.

**28 Claims, 7 Drawing Sheets**



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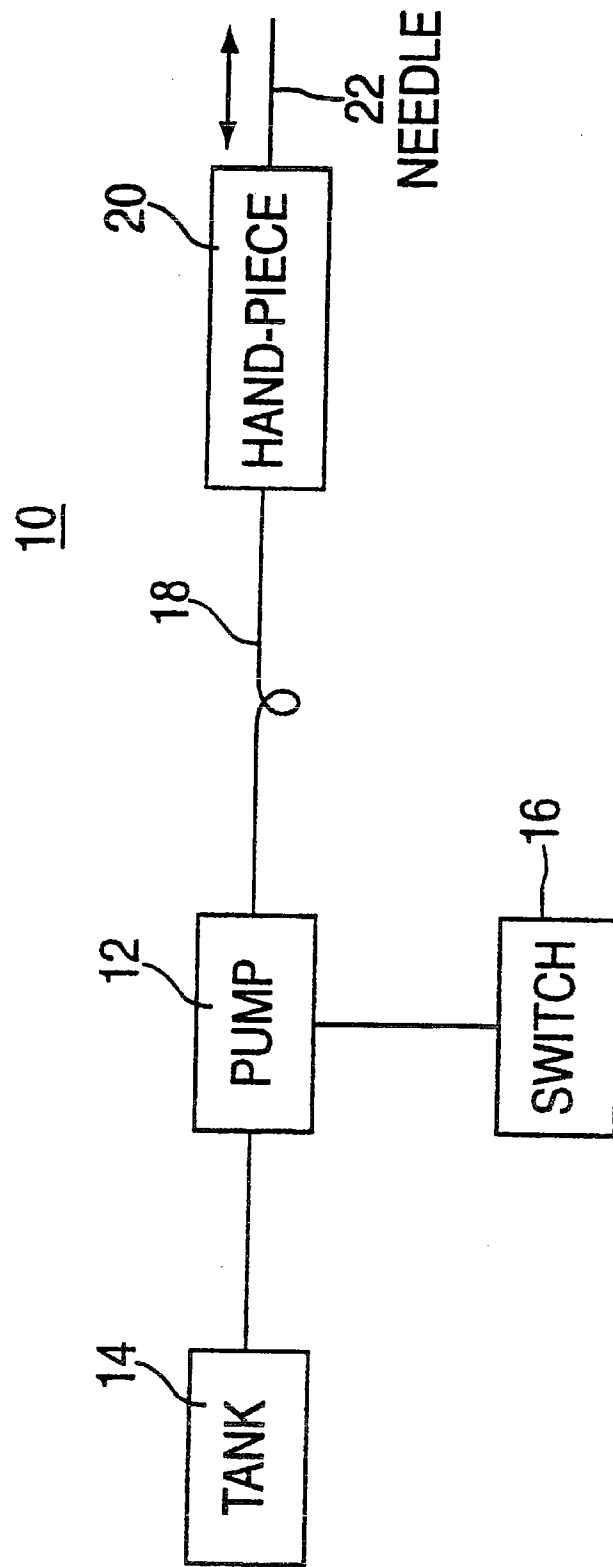
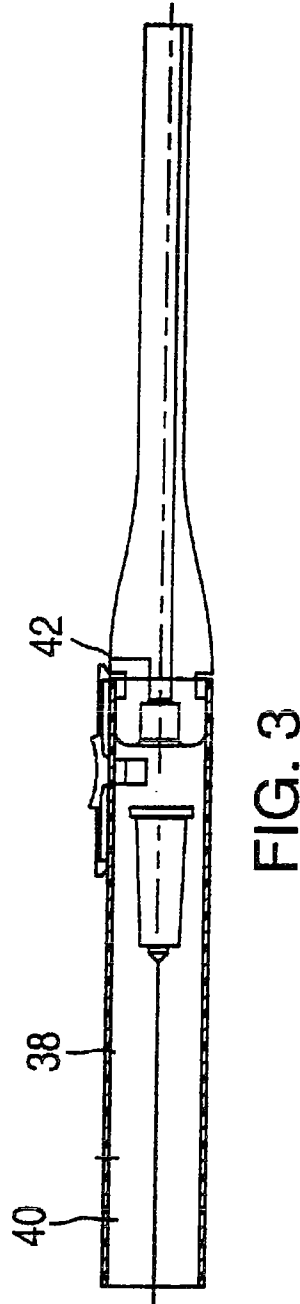
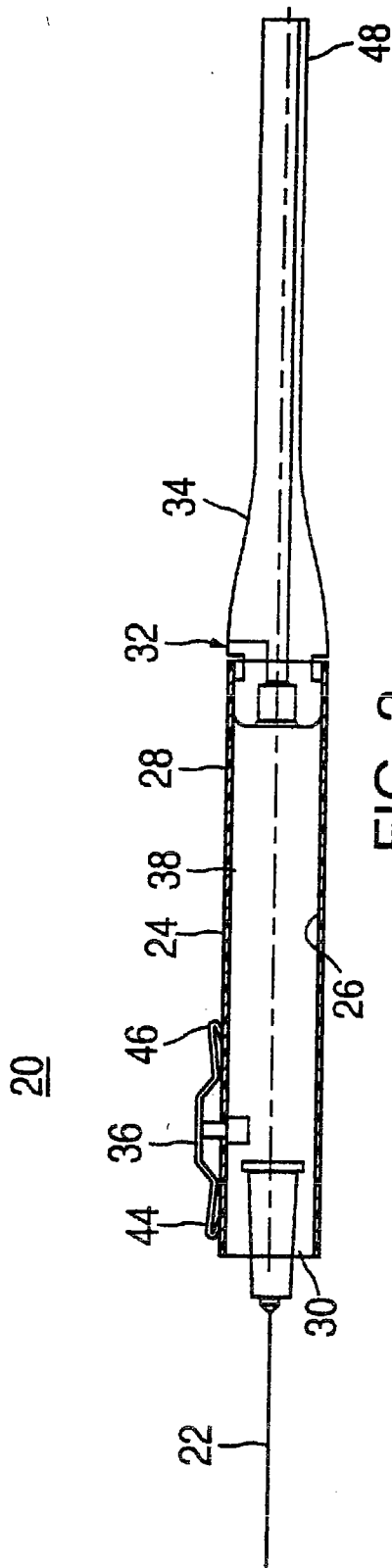


FIG. 1



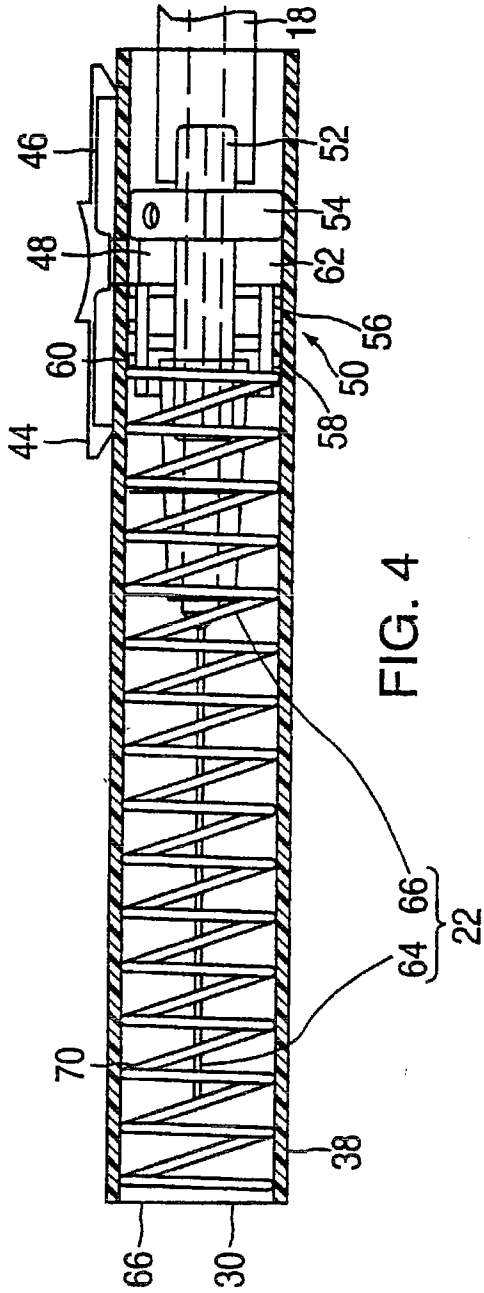


FIG. 4

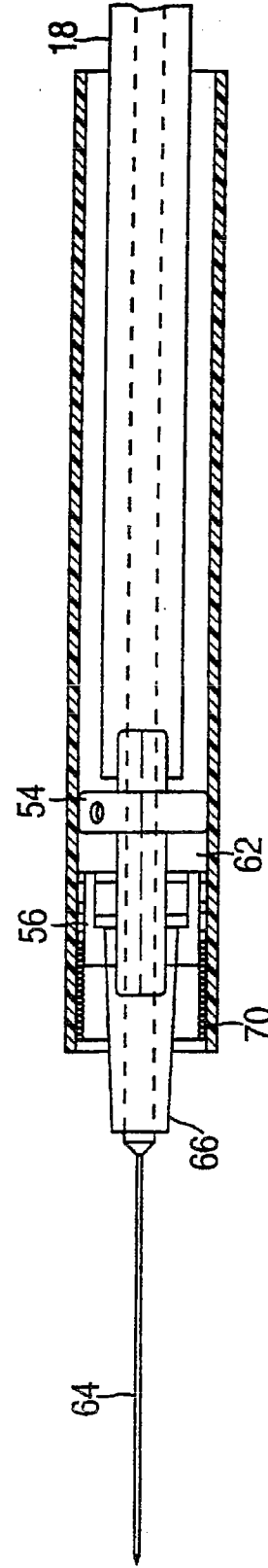


FIG. 5

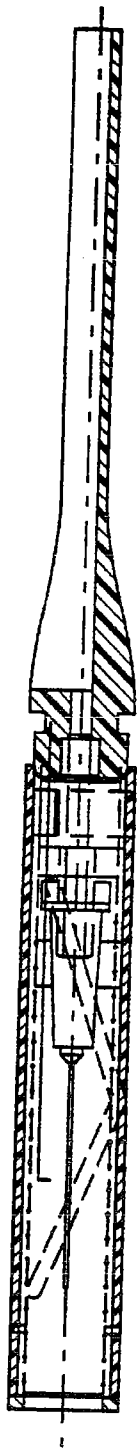


FIG. 6

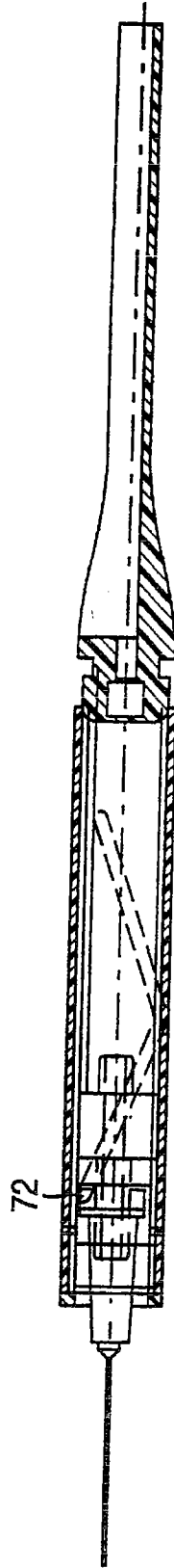


FIG. 7

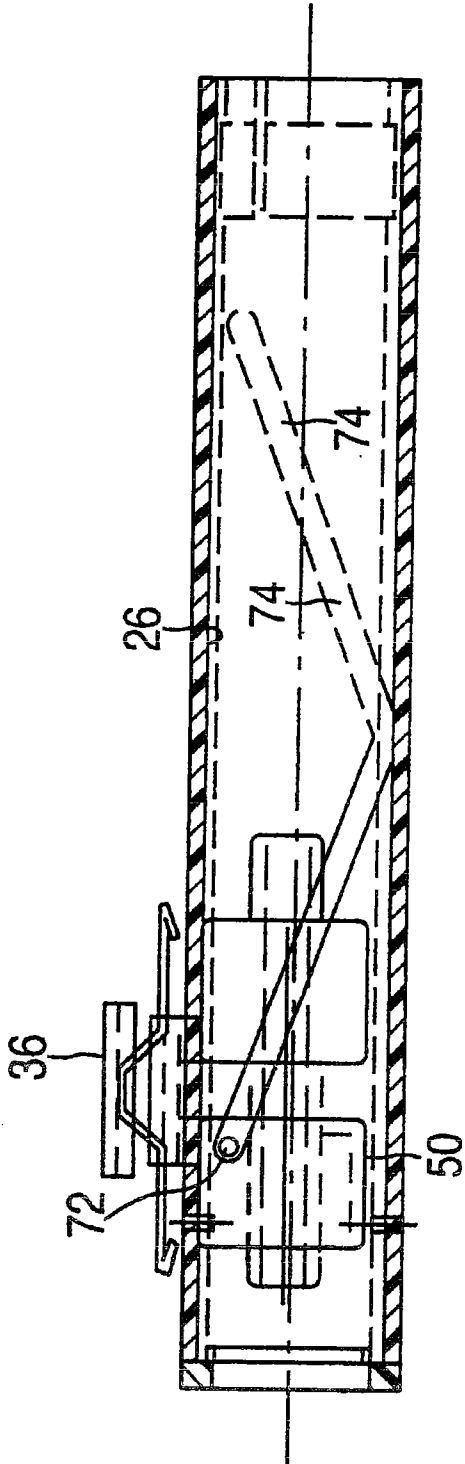


FIG. 8

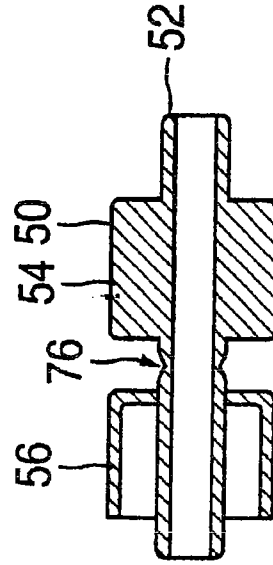


FIG. 9

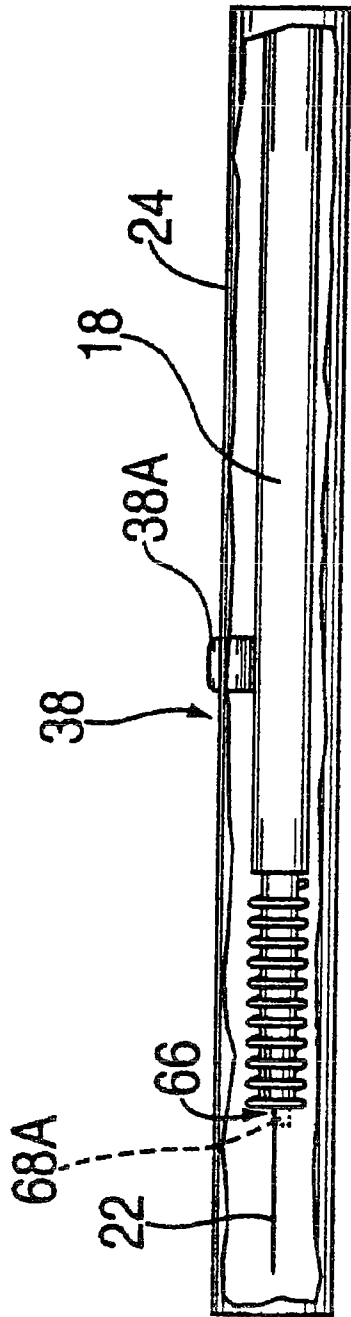


FIG. 10

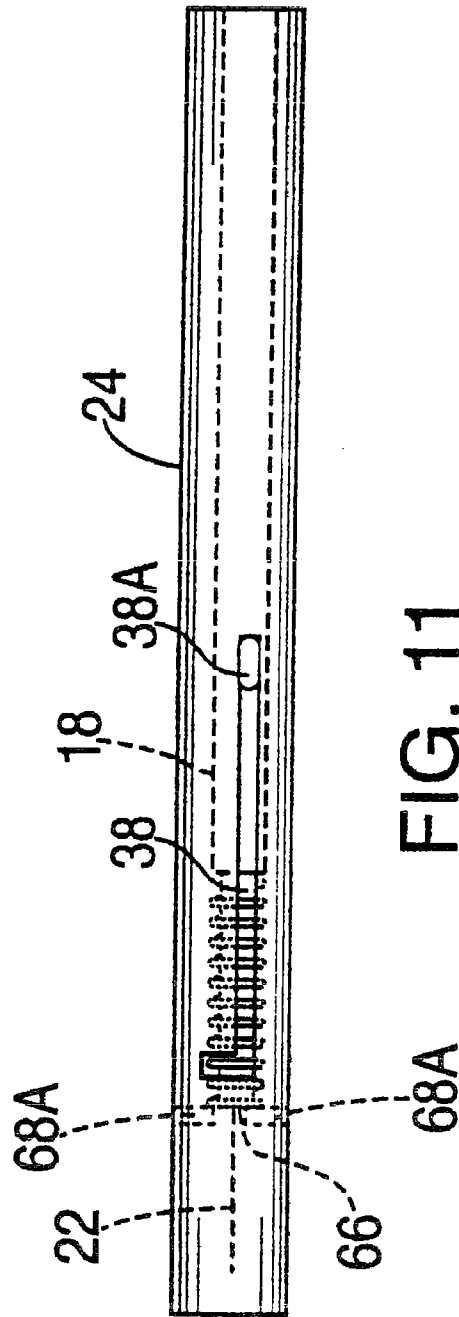
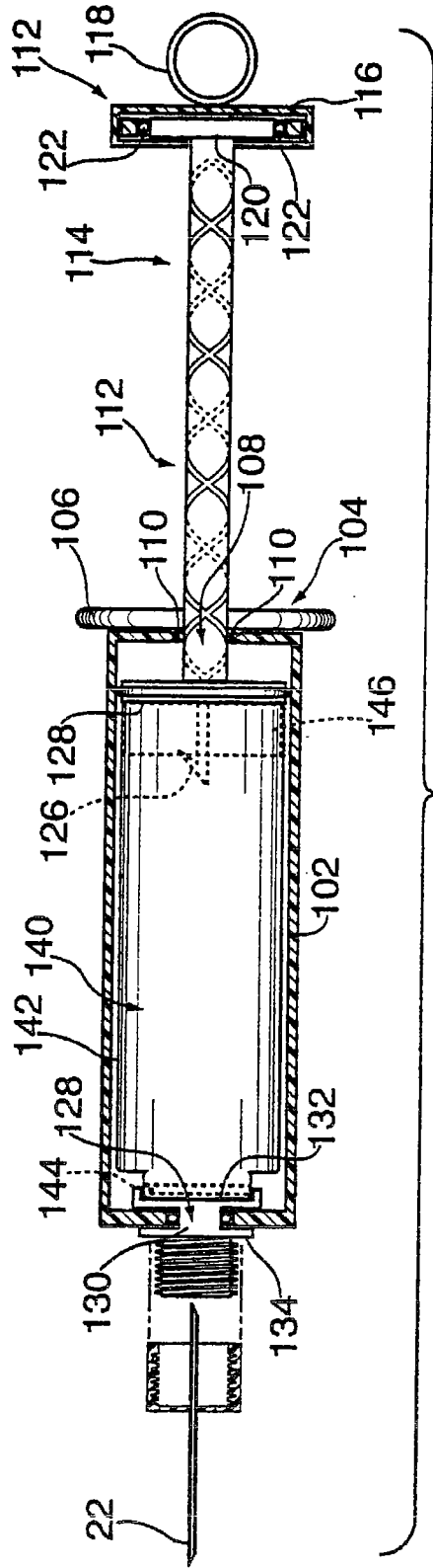


FIG. 11



**HAND-PIECE FOR INJECTION DEVICE  
WITH A RETRACTABLE AND ROTATING  
NEEDLE**

**RELATED APPLICATIONS**

This application claims priority to provisional applications serial No. 60/133,397 filed May 10, 1999 and serial No. 60/173,374 filed Dec. 28, 1999.

The subject matter of this application is related to co-pending application Ser. No. 09/745,751 filed Dec. 21, 2000 and entitled METHOD OF PERFORMING INJECTIONS USING A BI-DIRECTIONAL ROTATIONAL INSERTION TECHNIQUE, claiming priority to provisional application Ser. No. 60/173,374.

**BACKGROUND OF THE INVENTION**

**I. Field of the Invention**

This invention pertains to a hand-piece for an injection device or similar apparatus used to inject a therapeutic fluid into human or animal tissues, and more particularly to a hand-piece which includes a needle movable along a longitudinal axis, which needle is optionally rotating about said axis as well.

**II. Description of the Prior Art**

It is well documented in both dental and medical literature that pain, tissue damage and post-op complications have long been tolerated as negative side effects from the use of existing hypodermic drug delivery injection systems. The pain and tissue damage are as a direct result of uncontrolled flow rate in conjunction with excessive pressures created during the administration of drug solutions within the tissues. Subjective pain response of a patient has been demonstrated to be minimized at specific flow rates during the administration of a drug. Also, it has been scientifically demonstrated that particular pressures (excessive without occlusion, per se) for a specific tissue type will cause damage. It is therefore critical that a specific flow rate in conjunction with a specified pressure range be maintained during the delivery of fluids (drugs) when a subcutaneous injection is given preventing subjective pain response as well as tissue damage. It is also necessary that this system have the capability to aspirate under controlled conditions of rate and pressure to avoid the same negative side effects during fluid movement. U.S. Pat. No. 5,180,371 to Spinello, incorporated herein by reference, presented an invention which allowed a rate to be set for the drug via a hypodermic needle disposed in a hand-piece.

One of the goals of dentistry and medicine should be to administer care to patients in the most humane and painless manner. The sine qua non of any treatment is to produce a desired result without causing damage or pain to the individual. Therefore there is an important need in all fields of surgery for an injection system which can be used to administer a fluid while causing substantially no pain or tissue damage to the patient.

Another goal of dentistry and medicine in general is to insure that during any procedure involving interaction between a dentist or other care giver and a patient, utmost care is taken to protect the care giver from injury and/or infection with diseases.

The use of hollow-core needles is the standard in drug delivery in medicine and dentistry. The use of the hollow-core needle dates back over 150 years when Charles Pravaz, a French general surgeon, patented such a device. It has been recognized that the use of hypodermic needles, which activ-

ity is endemic in the field, is one particularly hazardous activity which could cause injury. More particularly, the use of a hypodermic needle in dentistry and other medical fields has been shown to put the operator at risk to inadvertent needle sticks presenting a potential high risk to infection disease transmission for health care workers.

Currently, there are several auto-retraction type syringes are known that provide increased safety by allowing the protruding needle to be retracted into a protective sheath after use. However, current syringes require the use of a palm-thumb grasp during their use. This type of hand dexterity presents a potential risk of inadvertent needle stick during entry and withdrawal from the patient tissues. Other syringes are provided with removable caps. However, this configuration does not solve the problem in a satisfactory manner.

All of these prior art references have either one or more of the following deficiencies.

1) The use of a hollow needle that is rigidly affixed to the end of a syringe-, tubing or hand-piece. The protruding needle presents a risk of inadvertent needle stick to the operator.

2) Existing auto-retracting syringes and the like require the operator to use a palm-thumb grasp to operate. This structure creates an increased risk of inadvertent needle stick to the operator.

3) Existing auto-retracting syringes and the like require the operator to make use of the hand to physically retract the needle, thereby, making it difficult and cumbersome to perform.

Some prior art syringes and needles with sheaths or caps are disclosed in the following U.S. Pat. Nos.: 5,120,310; 5,188,613; 5,267,961; 5,389,076; 5,423,758; 5,578,011; 5,632,733; 5,637,092; 5,810,775; 5,030,209; 4,911,693; 4,900,310; 4,813,426; 4,795,432; 4,664,654; 4,695,274; 4,966,592; 4,747,831; 4,900,311; 5,411,487; 5,106,379; 5,713,873.

With the rise of infectious diseases, i.e., hepatitis and AIDS, protection of the health care workers has become a needed priority because, as indicated in the medical/dental literature, inadvertent needle sticks represent a significant risk to our health care providers. In the past 15 years regulatory agencies such as OSHA have attempted to improve the use and safety of needles in the health care industry further accentuating the need for an effective means of preventing needle sticks.

In addition, various medical organizations have suggested and several states have instituted rules for the protection of care givers while providing injections to patients. More specifically, rules have been promulgated requiring that injection needles on syringes be provided which can be easily removed prior to an injection and re-installed immediately after an injection.

The proposed invention has been designed to eliminate the potential of inadvertent needle sticks during and after use.

Another related problem addressed by the present invention pertains to the deflection or bending of needles as they are inserted into the tissues of a patient. This deflection occurs because the needle is usually flexible because of its relatively small cross-sectional area and cannot resist effectively the axial and radial forces present during the insertion. The deflection is undesirable because it provides additional resistance during the insertion, to the movement of the needle and makes it difficult to guide the needle to a

particular site. Moreover, if a needle is deflected, bent or otherwise deformed during insertion, it may cause more pain to the patient, trauma to the local tissues and other undesirable effect. It has been discovered (as disclosed in co-pending provisional application serial No. 60/173,374 filed Dec. 28, 1999), incorporated herein by reference, that these disadvantages are eliminated or at least alleviated if the needle is rotated about its longitudinal axis as it is advanced along the axis into the patient tissues. While rotating devices are known which rotate about their longitudinal axes to allow drilling through bony tissues, these devices do not allow high level tactile control during use. Other syringes do not allow the use of a bi-directional rotational insertion technique to be used during a power assisted injection process.

### OBJECTIVES AND SUMMARY OF THE INVENTION

In view of the above-mentioned disadvantages of the prior art, an objective of the present invention is to provide an injection device having a needle which can be selectively advanced from a retracted position in which the needle is hidden, toward an open position in which a therapeutic agent can be administered effectively, and can be retracted back to the retracted position before disposal.

A further objective is an injection device adapted to provide injection to a selected site and/or tissue by using a selective bi-directional rotational movement of the needle to prevent deflection of the needle.

Yet another objective is to provide an injection device which allows an operator to advance a needle at a manually controlled rate and with a hand-piece which is held steadily in a relatively stationary position with respect to the patient.

A further objective is to provide an injection device which can be used repeatedly to advance and retract a needle in a linear, rotational or bi-directional rotational motion.

Other objectives and advantages of the invention shall become apparent from the following description.

Briefly, an automatic injection device constructed in accordance with this invention includes a source of fluid to be injected, a needle, handle with a housing and a coupling used to selectively advance the needle out of the hand-piece, preferably under the control of the operator, and once an injection is complete, to retract it back into the hand-piece. Advantageously, the needle may be protracted and retracted several times during multiple uses on the same patient. The device may be a drug delivery device which serves to inject medicament from a tank or reservoir. This includes but should not be limited to infusion type pumps, syringe pumps, such as the Wand® made by Milestone Scientific of Orange, N.J.

In one embodiment, of the invention, a spring is provided in the housing which is arranged to bias the needle. Preferably the needle is biased toward its retracted position so that if the needle is advanced to extend outwardly of the housing and then released, it automatically returns to the retrieved position within the housing thereby reducing the likelihood that the needle pricks or otherwise injures an operator, the patient, or anyone else. Locking members are also provided which are used to secure the needle in the first—that is—the retrieved position, or the second position. The coupling may be arranged and constructed to cooperate with the housing so that as the needle is advanced out of the housing, it is automatically and simultaneously rotated about its longitudinal axis. Typically, the needle may be rotated by about 45–270°. Preferably the needle is rotated by about 180°.

This may be accomplished, for instance, by providing a helical groove on an inner surface of the housing and a boss on the coupling. As the coupling moves through the housing, its boss rides through the groove and this camming action causes the coupling, and the needle to rotate. If the groove is oriented in the same direction, the rotational motion is uni-directional. The groove can also be made to change direction one or more times along its length, in which case the needle undergoes a bi- or multi-directional motion. The term uni-directional is used to describe motion in the same sense, e.g., clockwise or counterclockwise. The term bi-directional is used to describe a motion that changes sense, e.g., initially clockwise, then counterclockwise.

Rotation may also be imparted to a needle affixed to a standard syringe. In this case, the needle is mounted to one wall of the barrel using a ball-bearing mounted, or other frictionless surface. A plunger is coupled to the other side of the barrel in a manner which forces the plunger to rotate as it is inserted into the barrel to force liquid from the barrel to be ejected through the needle. The plunger and the needle are coupled so that the rotation of the plunger is transmitted to the needle.

### BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 shows a somewhat schematic diagram of an automatic injection device constructed in accordance with this invention;

FIG. 2 shows a sectional somewhat diagrammatic view of the hand-piece for the device of FIG. 1 with the needle in an extended position;

FIG. 3 shows a sectional view similar to FIG. 2 with the needle in the retracted position;

FIG. 4 shows a sectional view of the needle and a spring used to bias the needle toward the retracted position;

FIG. 5 shows a sectional view of the needle and the spring in the extended position;

FIG. 6 shows an embodiment of the invention which allows the needle to rotate about its axis, the needle being in a retracted position;

FIG. 7 shows a view similar to FIG. 6 with the needle being in the extended position;

FIG. 8 shows an enlarged view of the needle coupling and its engagement with a spiral groove;

FIG. 9 shows an enlarged side view of the coupling;

FIG. 10 shows a side view of a hand-piece according to an alternate embodiment of the invention wherein the helical groove has been omitted;

FIG. 11 shows a top view of a hand-piece according to an alternate embodiment wherein the slot holding the button or tab has side wing or wings; and

FIG. 12 shows a sectional view of a hand-piece according to an alternate embodiment of the invention

### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

In order to better understand the purpose of this invention, a somewhat generic automatic injection device is first described. In this application the term automatic injection device, as illustrated in FIG. 1 refers to a device 10 in which a fluid ejection means such as a pump 12 is used to force a fluid from a tank 14 under the control means such as a switch 16 into a flexible tubing 18. The tank may be a vial, a carpule or other known vessels that could be used to store a therapeutic liquid. The tubing 18 terminates in hand-piece

20 with a needle 22. The various elements described so far cooperate to allow a nurse, physician, dentist and other health care professional operator to inject selectively the liquid from tank 14 into the tissues of a patient (not shown) by activating the switch 16.

Importantly, according to this invention, the needle 22 is movable into and out of the hand-piece 20. In a preferred embodiment, the needle 22 is normally disposed inside the hand-piece 20 and is extended by the operator prior to or simultaneously with the injection. After the injection is complete, the needle 22 is preferably retracted into the hand-piece 20. In this manner, the needle 22 is exposed only the short periods of time that the injection actually occurs, thereby preventing injury and infection to the operator of the device 10 or other people. Studies have shown that a person handling a device associated with a needle is injured during this period.

Advantageously, the hand-piece 20, needle 22 and the tubing 18 are generally disposable. Moreover, the cap normally provided to cover the needle is eliminated, so it is no longer required.

Details of the hand-piece 20 and needle 22 are now discussed in conjunction with FIGS. 2-9. The hand-piece 20 includes in accordance with this invention a cylindrical housing 24 with an internal wall 26, an external wall 28, and two ends 30, 32. Hand-piece further includes an elongated hollow stem 34 provided to protect the tubing 18. The tubing 18 which extends through the stem 34 into the housing 24 and is coupled directly or indirectly to the needle 20 as discussed more fully below. Stem 34 may be glued to the housing 24, or may be sized and shaped to form an interference fit therewith, whereby it can be inserted into the housing 24 or removed at will.

Mounted on housing 24 there is a control member such as a button 36 slidable in a longitudinal slot 38 extending through the housing. Housing 24 is provided with a stop 40 at the forward end of slot 38. The rear end 42 of the housing 24 serves as a rear stop for button 36. Alternatively, a stop similar to stop 40 may be provided on the external wall 28 of housing 24. Button 36 includes two spring arms 44, 46. These arms extend in the longitudinal axis of the housing 24 and are turned upward, or away from surface 28 at their tips. These arms 44, 46 are somewhat flexible and cooperate with the stop 40 and end wall 42 to limit the movement of button 36 in slot 38. More particularly, as button 36 is reciprocated by an operator in slot 38, when the button reaches its forward position, the arm 44 rides over the stop 40 and then snaps radially inward to form an interference fit with the stop 40. This position (shown in FIG. 2) corresponds to the extended position of the needle 20, with the button 36 being locked. The button 36 can be released by pressing it downward toward the housing 24, thereby causing arms 44, 46 to flex upward. The button 36 can then move backward, away from the front opening 30 because the arm 44 clears the stop 40. When the button 36 is moved backwards toward stem 34, when its rear arm 46 engages the rear wall 42, the button 36 is locked into the rear position, and the needle 22 is in its fully retracted position, as indicated in FIG. 3.

Button 36 further includes a pin 48 extending downwardly or radially through slot 28 to engage needle 20. Button 38 can be made of a high impact plastic material. Its wings 44, 46 can be made integral with the button 38, or can be made of steel.

Referring now to FIGS. 4 and 5 (in which the stem 34 has been omitted for the sake of clarity) the needle 20 is attached to a coupling 50. This coupling includes a central hollow

shaft 52 sized and shaped to connect to an end of tubing 18. Preferably the tubing 18 is glued or otherwise secured to the shaft 52 so that it is permanently mounted thereto.

The coupling also has a circular disc 54 mounted coaxially on the shaft 52. Spaced axially away from disc 54 there is cup-shaped adapter 56. Adapter 56 has an outer surface 58 with a plurality of axially shaped circumferential ribs 60. The disc 54 and adapter 56 are separated by an annular space 62 having an axial length which is equal to, or slightly greater than the cross-sectional dimension of pin 48. The length of the housing 24 and the button 36 is positioned on the housing 12 so that this pin 48 extends into the space 62 as shown. Therefore the coupling 50 and the button 36 are effectively interlocked so that the coupling 50 can be moved in either direction along the length of the housing 24 and the button 36 will move with it (within the length of the slot 38) and vice versa. However, because space 56 is annular, the coupling 50 may also rotate around the longitudinal axis of housing 24 without interference from button 36.

Typically, needle 22 includes a narrow, thin-walled hollow shaft 64 and a base 66. In one embodiment of the invention the needle 22 is configured with the base 66 being mounted on shaft 52 so that it abuts the adapter 50. Base 66 is preferably bonded or otherwise secured to the shaft 52 and/or the adapter 56. The base 66 is hollow and in communication with the opening in the hollow shaft 64. Therefore, once the base 66 is mounted and secured to the adapter 56, the interior of tube 18 is in communication with the interior of the shaft 64 through the shaft 52.

Preferably, the end 30 is partially closed with a disc-shaped end wall 68. This end wall 68 has an opening (not shown) sufficiently large to allow the needle 22 and its base 66 to extend at least partially from housing 24, as seen in FIG. 5.

In one embodiment of the invention, as mentioned above, the base 66 is bonded to adapter 54. In another embodiment of the invention, the adapter 54 is a female Luer connector and the base 66 is a male Luer connector, the two connectors cooperating to mount the needle 22 on the coupling 50 so that the needle 22 can be attached and removed at will. This feature may be advantageous during a long procedure the tip of the needle 22 may become dull and may have to be changed before the procedure is complete.

In another embodiment of the invention, an optional compression spring 70 is provided between the end wall 68 and the coupling 50 in such a manner that normally the spring 70 pushes the coupling 50, and the needle 22 attached thereto, away from wall 68. In other words, in this embodiment, the spring 70 urges the needle 22 toward its retracted position.

Yet in a further embodiment of the invention, shown in FIGS. 6, 7 and 8, the coupling 50 is provided with a boss 72 extending radially, and the inner surface 26 is provided with a helical groove 74, with the boss 72 being seated with the groove 74 as shown. In this embodiment, coupling 50 and the needle 22 attached thereto are rotatable about the longitudinal axis of housing 24. Coupling 50 with its boss 72, and groove 74 define a rotating member that cooperate with the button 36 so that the translational movement of button 36 along the housing 24 in slot 38 causes a simultaneous translation and rotation of the needle 22 as the needle moves between its retracted and protracted positions.

The operation of device 10 is now described in conjunction with the drawings. Initially, it is assumed that device 10 has a hand-piece which has been provided with a spring 70 and groove 74. Prior to an injection the needle 22 is disposed

