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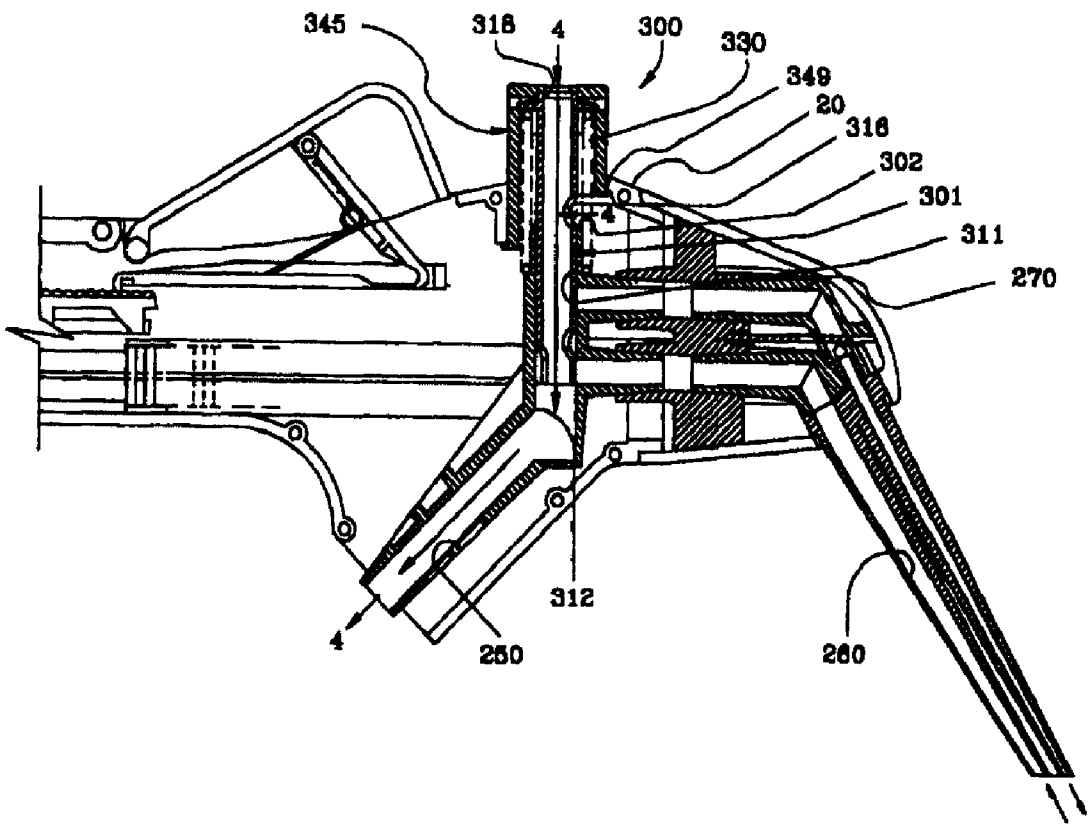

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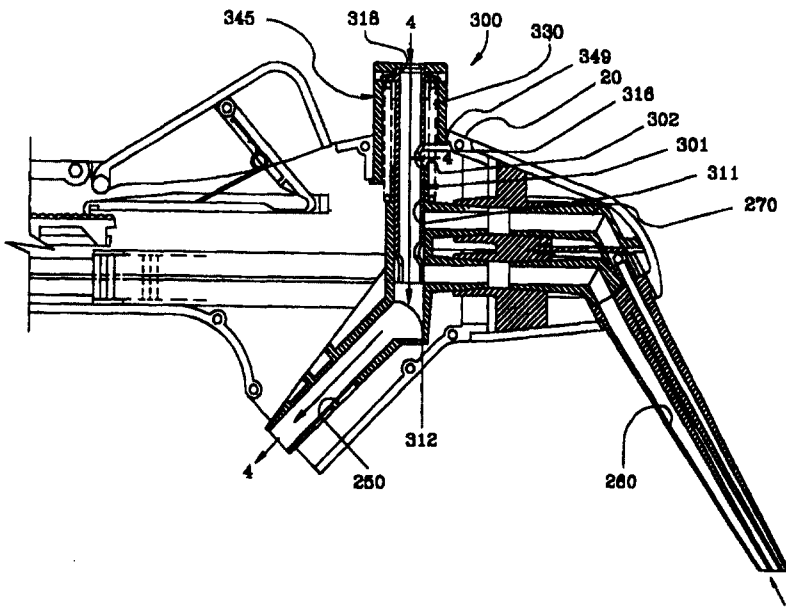

(57) Abstract

A medical fluid suction device for selectively applying varied levels of suction pressure at a device tissue interface includes a direct "trumpet" type control mechanism in conjunction with a "venturi" type control. A valve manifold (300) is adapted to couple a vent pathway and a suction pathway (260) simultaneously to the vacuum conduit adapted for connection to a vacuum source. The amount of resistance to flow due to vacuum pressure is adjusted simultaneously in both the vent pathway and the suction pathway (26) in order to achieve controlled, selected levels of suction. Similarly shaped valve apertures are provided in inverse and reciprocal orientation along an axis of motion of a valve manifold (300).

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MEDICAL SUCTIONING APPARATUS AND METHODS OF USE

CROSS-REFERENCE TO A RELATED APPLICATION

The subject matter of the present application is related to that of our copending international application of like filing date entitled FLUID APPLICATOR FOR DISPENSING MEASURED QUANTITIES WITH USE OF CONTROLLED SUCTION, the disclosure of which copending international application is hereby incorporated herein by reference thereto.

TECHNICAL FIELD

The invention relates to a suction applicator, and methods of using the applicator, which applicator is intended to be manually held and operated. The applicator has applications as a medical device, for example to provide a range of controlled levels of applied suction to a work surface such as biological tissues during surgery or other medical treatment. In preferred embodiments the applicator is a medical fluid suctioning device which is combined with a dispensing assembly in a biological tissue sealant (or adhesive) applicator which selectively provides controlled levels of suction force at a suction conduit in the applicator tip as well as tissue adhesive application.

BACKGROUND

Various medical devices have been disclosed which are adapted to either dispense fluids onto body tissues, suction fluids from body tissues, or to perform a combination of dispensing and suctioning fluids. Examples of such prior disclosure are provided in an overview fashion below.

Various known suction devices have been adapted for different medical applications. In such suction devices, several valve structures have been used to control and vary the amount of suction. These known valve mechanisms for medical suction devices generally: adjust the fluid communication with vacuum directly to the working tip, or alternatively, adjust the proportion of vacuum pressure directed to a vent pathway in parallel with the suction tip. Often, the specific valve structures for adjusting fluid passageways for suction are referred to as stopcock (1,2, or 3-way), gate, pinch, trumpet, or venturi valves.

Examples of suction devices using valve structures which adjust fluid communication directly with the vacuum source are disclosed in U.S. Patents Nos.: 3,645,497; 4,487,600; 4,504,266. Such devices which also combine fluid dispensing include U.S. Patent Nos.: 2,812,765; 3,208,145; 4,696,669; 4,776,840; 4,891,044; 5,061,180; 5,186,714; 5,295,956; 5,476,450; 5,603,700. Furthermore, such devices that adjust suction in a variably-controlled amount are disclosed in U.S. Patent Nos. 3,645,497;

4,776,840; and 5,368,560.

One type of mechanism such as that just described is a "pinch valve", such as is disclosed in U.S. Patent Nos. 4,696,669 and 5,295,956. U.S. Patent No. 5,295,956 to Bales et al. discloses a pinch valve providing variable suction control in a hand-held endoscopic suctioning device. In this device, a suction passageway is held closed by a spring-loaded hook (preferably plastic) which is attached to a trigger button. Upon "pulling" the trigger, the attached hook relieves the compression of the flexible tubing, opening the suction passageway. Hence, depending on the displacement of the trigger button, the suction may be controlled.

Similar to pinch valves, trumpet valves also affect fluid communication between the vacuum source and the working tip. Rather than constrict the passageway, however, the trumpet valve functions by controlling the degree of blockage in the suction passageway; thereby adjusting the amount of fluid flowing through the suction passageway.

For example, U.S. Patent No. 3,645,497 to Nyboer discloses a hand-held variable controlled suction device adapted for use in dental applications. The passageway connecting the vacuum source to the working tip is entirely blocked by a thin plate when the user desires no vacuum pressure. Alternatively, to increase vacuum pressure at the working tip, the user can slide the plate in variable amounts; resulting in an increase or decrease in the amount of fluid flow through the passageway.

A hand-held medical evacuator and irrigation device is disclosed in U.S. Patent No. 4,776,840 to Freitas. Basically, two ports exist at the working end. One port is directly connected to a vacuum source and the other port either dispenses solution or provides a vacuum. In addition to the constant vacuum port, a second, and adjustable, suction is created by pressing a conveniently located plunger with the user's thumb. By depressing the plunger, the vacuum source communicates with the dispensing port and simultaneously prevents any backflow from contaminating the fluid reservoir. Furthermore, the plunger is tapered which, depending on its displacement, adjusts fluid flow (suction) between the vacuum source and the dispensing port.

In addition to trumpet-type valves, suction may be adjusted by changing the proportion of vacuum pressure directed to a vent pathway in parallel to the working suction tip. These structures are herein referred to as "venturi"-type structures. When the vent pathway is covered, vacuum pressure at the working tip is greatest and all suction is through the passageway. On the other hand, when the vent pathway is open, suction is primarily through the vent pathway and the working tip sees little suction.

Furthermore, the amount of vacuum pressure may be adjusted in proportion to the amount of fluid flow through the vent pathway. However, when the working tip is occluded, this control is generally believed to have little sensitivity because most suction flows through the vent pathway.

Examples of venturi-type valves used in medical suction devices are described in the following U.S. Patents Nos.: 3,469,582; 3,625,221; 4,356,823; 4,445,517; 4,617,013; 4,699,138; 4,857,047; 5,024,615; 5,226,877. These devices, which also dispense solution, are disclosed in U.S. Nos.: 4,617,013; 4,857,047; and 5,226,877. In U.S. Patent No. 3,625,221, adjustable venturi suction is disclosed and in U.S. Patent Nos. 5,419,769 and 3,469,582, a venturi suction actuates another member to communicate fluid flow between the vacuum source and the working tip.

In particular, U.S. Patent No. 5,024,615 to Buchel discloses a suction device used for surgical operations with a venturi-type valve used to adjust vacuum pressure. The amount of fluid flow through the vent pathway is adjusted by the user's finger-tip and accordingly, the vacuum pressure at the working tip of the device is adjusted.

In addition to trumpet and venturi-type mechanisms described above, another device structure creating mild suction is disclosed in U.S. Patent No. 5,300,022 to Klapper et al. Here, however, suction is created as an irrigating solution flows across a drainage (vacuum inlet) port at the working tip. Due to the cone shaped structure, the irrigating solution is deflected downward away from the drainage port, creating a mild venturi suction.

U.S. patent 5,226,877 to Epstein disclose a tissue sealant applicator which has a suction applicator tip and which references simultaneous application of sealant and suction. In fact the described operation of the applicator envisages applying suction and sealant in separate passes. Clearly, what is intended is that the operator can switch between suction and sealant while operating the applicator with one hand, but apparently, only one fluid, suction or sealant, is intended to be dispensed at any given moment. Though this is a useful method, there is a need for an improved method of tissue sealant application.

In addition to the cited references provided above, further disclosures of suction devices are disclosed in U.S. Patent Nos.: 1,206,126; 3,065,749; 3,949,748; 4,573,979; 4,904,328; 5,024,654; 5,145,367; 5,348,542; 5,433,705.

In summary, known suctioning devices that are capable of providing a range of suction levels, varying from low intensity suction to high intensity suction, are prone to abrupt changes in the intensity of suction

output, provide too little control of gentle suction, have uneven response characteristics, may grab and hold delicate work surfaces such as surgical tissues, or suffer from a combination of these disadvantages. Accordingly, there is still a need for a manually operable suctioning device, suitable for medical applications, that provides a controllable selection of suction levels at a working tip with a balanced response to applied manual effort throughout the range of suction levels.

SUMMARY OF THE INVENTION

The present invention solves a problem. It solves the problem of providing a suction applicator, suitable for medical uses, which fulfils one or more of the above-described needs. Other problems solved by the several aspects of the invention and particular embodiments thereof will be apparent from the disclosure herein.

Accordingly, in one aspect, the invention provides a suction applicator intended to be manually held and operated and comprising:

a) a suction applicator tip to apply suction at a work surface;

b) a suction connector connectable with a suction source;

c) a suction pathway extending between the suction connector and the applicator tip in an operative configuration of the applicator;

d) venting means connectable to vent the suction pathway to atmosphere; and

e) a manually operable suction control member to control suction at the applicator tip;

wherein the suction control member is selectively movable between a first position providing full venting of suction to atmosphere with no suction applied to the applicator tip and a second position with no venting to atmosphere and full suction applied to the applicator tip wherein the suction control member has an intermediate position wherein the suction pathway is partially constricted to apply partial suction to the applicator tip and partially vented to atmosphere.

In a preferred embodiment, the suction control member is movable to a third position wherein the suction pathway is connected with the dispensing pathway to clear the dispensing pathway. Optionally a fourth position can close off the suction pathway, without venting.

In another aspect, the invention provides a suction applicator intended to be manually held and operated and capable of supplying from an external suction source, a controllable suction flow at a range of different intensities, the applicator comprising:

a) a suction applicator tip to apply suction at a work surface;

b) a suction connector connectable with the external suction source;

c) a suction pathway extending between the suction connector and the applicator tip in an operative configuration of the applicator;

d) venting means connectable to vent the suction pathway to atmosphere; and

e) a manually operable suction control member to control suction at the applicator tip;

wherein the venting means comprises a variable venting throat operable by the suction control member to vary the extent of venting of the suction pathway. Preferably, the suction pathway comprises a variable suction throat operable to vary the suction applied to the applicator tip and the venting throat and the suction throat are coupled together to vary inversely as the suction control member is moved. In this aspect also, the suction control member can be movable to a clearing position where the suction pathway is connected with the dispensing pathway to clear the dispensing pathway of undesired material.

The invention is particularly, but not exclusively, useful for medical applications such as the application of a biological tissue sealant, which may optionally be premixed in the applicator, and for this purpose the applicator comprises a dispensing tip for such a fluid disposed adjacent the suction applicator tip for cooperative application of suction and the tissue sealant to a work surface.

In a still further aspect the invention provides a medical suction device, comprising:

a) a housing;

b) a suction applicator tip extending distally from the housing and terminating in a suction aperture;

c) a suction conduit extending within the housing between a proximal suction port and the suction applicator tip;

d) a vacuum conduit connectable to a vacuum source; and

e) a vent in communication with atmospheric pressure,

characterized by comprising:

f) a movable valve manifold coupled to the proximal suction port and the vacuum conduit, the valve manifold being adapted to distribute vacuum pressure from the vacuum conduit between the suction conduit and the vent in a variable manner;

and by the valve manifold being manually movable between a first position wherein the suction conduit is isolated from the vacuum conduit and the vent is in fluid communication with the vacuum conduit, and a second position wherein the suction conduit is in communication with the vacuum conduit and the vent is isolated from the vacuum conduit.

In one embodiment, the vacuum manifold comprises:

i) a valve housing having a suction port in fluid communication with the suction conduit and having a vent port providing the vent in communication with atmospheric pressure; and

ii) a valve member movable within the valve housing between said first and second positions and including a vacuum chamber in fluid communication with the vacuum conduit, a suction aperture and a vent aperture, the suction and vent apertures being constructed and disposed to translate across and register at least in part with the suction and vent ports, respectively, as the valve member moves between said first and second positions.

Preferably, the suction and vent apertures are configured with a transverse dimension which varies in the direction of motion of the valve member, and are inversely oriented whereby, as the valve member moves, relative to respective stationary points, the transverse dimension of the suction aperture increases while that of the vent aperture decreases, and *vice versa*.

Thus, the invention provides a medical suctioning device which inversely and reciprocally adjusts the proportion of applied suction between a suction pathway in a working tip and a vent pathway. By controllably managing both the suction pathway and a venting pathway with variable throat valving, the invention provides a suction applicator well suited to the needs of surgeons, especially needs that may arise in connection with the application of tissue adhesive, which provides sensitive control of gentle aspiration, a moderate suction range and good control of full suction, by means of a single manually operable control member having a smooth action, good feel and response.

In a still further aspect, the invention provides a method of applying a tissue sealant employing a tissue sealant applicator having a tissue sealant output aperture and a suction application aperture adjacent thereto comprising moving the applicator across the tissue surface in a direction whereby the suction application aperture leads the tissue sealant output aperture while applying the suction to prepare the work surface and applying sealant to the prepared work surface. Thus the surgeon or other user can simultaneously prepare a work surface and apply sealant to the work surface, in a single pass.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a medical fluid applicator assembly which includes, in part, a fluid suctioning device assembly embodiment of the present invention.

Figures 2A-C are top plan, side elevational, and end elevational views of the medical fluid applicator assembly of Figure 1.

Figure 3 is an exploded perspective view of the medical fluid applicator assembly of Figure 1, showing an applicator portion removed from a supply device portion, and further showing the internal structure of the respective portions in shadow, as well as exploded schematic views of portions of an actuating assembly, an audible volume indicator, and a valve manifold included in

the fluid suctioning device assembly of the present invention.

Figures 4A-B are side elevational sectional and top elevational sectional views, respectively, of proximal portions of the fluid dispensing pathway of the medical fluid applicator assembly of Figure 1, wherein Figure 4B is taken along line 4B-4B of Figure 4A.

Figure 4C is a perspective view of the applicator portion of the assembly of claim 1, further showing a dispensing conduit in shadowed view as the distal end portion of a fluid dispensing pathway.

Figure 5 is an elevational sectional view of the dispensing assembly of the medical fluid applicator assembly of Figure 1, taken through the center of the device along line 5-5 of Figure 2A.

Figure 6 is a top plan view of a rack used in an actuating assembly and in an audible volume indicator included in the medical fluid applicator assembly of Figure 1.

Figure 7 is a top plan view of the plungers used with the rack in the actuating assembly of the medical fluid applicator assembly of Figure 1.

Figure 8 is a similar elevational sectional view of the medical fluid applicator assembly as shown in Figure 5, although showing both the supply device portion and the applicator portion in sectional view to show the suction assembly of the current invention.

Figures 9A-E are top elevational, bottom elevational, side elevational sectional, user end elevational, and working end elevational views, perspectively, of the valve stem used in a valve manifold of the suction assembly shown in Figure 8, wherein Figure 9C is taken along line 9C-9C of Figure 9A.

Figures 10A-D are top elevational, bottom elevational, and two side elevational sectional views, respectively, of the valve actuator used to actuate the valving of the suction assembly of Figure 8, wherein Figure 10C is taken along line 10C-10C and Figure 10D is taken along line 10D-10D of Figure 10A.

Figures 11A-D are top plan, side elevational, side elevational sectional, and end elevational sectional views, respectively, of a shuttle valve which coordinates dispensing and clearing mechanisms of a dispensing conduit provided in the overall medical fluid applicator of Figure 1, wherein Figure 11C is taken along line 11C-11C of Figure 11A, and Figure 11D is taken along line 11D-11D of Figure 11B.

Figures 12A-C are exploded side elevational sectional views of the suction assembly of Figure 8, showing a valve stem in three sequential positions within the valve manifold housing which correspond to an open vent pathway, an open suction pathway, and an open clearing pathway, respectively.

Figures 13A-B are schematic representative views of the valve manifold of the current

invention during sequential modes of operation, respectively, in selectively and controllably adjusting the amount of applied suction to the suction pathway of Figure 12B.

Figures 14A-B are schematic representative views of the valve manifold during sequential modes of operation, respectively, in shuttling applied vacuum from the suction pathway of Figure 12B during fluid application to the clearing pathway of Figure 12C following fluid application, respectively.

Figure 15 is a perspective view of one preferred filling dispenser assembly used to fill the dispensing assembly of the supply device portion of the medical fluid applicator of Figure 1.

Figure 16 is a perspective view of the dispenser assembly of Figure 15 with the supply device portion of the medical fluid applicator of Figure 1 engaged thereto in a predetermined filling orientation.

Figure 17A is a top plan view of the filling dispenser assembly shown in Figure 15.

Figure 17B is a sectional elevational view taken along line 17B-17B of Figure 17A.

Figure 17C is an exploded sectional elevational view of one supply device coupling region shown in Figure 17B.

Figure 17D is a similar sectional elevational view to Figure 17B, except taken along line 17D-17D of Figure 17A.

Figures 18A-C are side perspective, top perspective, and user end perspective views, respectively, of further actuating trigger and applicator tip variations adapted for moderately invasive surgery applications of the medical fluid applicator variation of the current invention.

Figures 19A-D are top perspective, side perspective, end perspective, and sectional perspective views of a medical fluid applicator of the present invention with a further variation in the conduit lumen arrangement at the applicator tip portion, wherein Figure 19D is taken along line 19D-19D of Figure 19A.

Figures 20A-C are exploded views of the applicator tip portion of the assembly shown in Figure 19D, showing the valve manifold in sequential modes of operation in creating a vent pathway, a suction pathway, and a clearing pathway, respectively.

DETAILED DESCRIPTION OF THE INVENTION

The present invention will be illustrated by means of a preferred embodiment shown in the drawings. The medical fluid suctioning device of the present invention is useful as a stand alone suctioning device. However, it is to be appreciated by the illustration and description below of one preferred embodiment that the suctioning invention is useful in combination with various features of a dispensing assembly to form an overall medical fluid applicator.

Detailed description of the suctioning device of the present invention is therefore provided as one part of an overall disclosure of the preferred mode of operation in a combination medical fluid applicator device having several assemblies and sub-assemblies described. Figures 1-2C provide various perspective views of the overall combination medical fluid applicator assembly. Figure 3 provides an overview of the removably engageable supply device and applicator portions of the overall device, as well as the overall interior workings of the dispenser and the suction assemblies of the device. Figures 4-7 provide increasing detail regarding the dispenser assembly aspects of the present invention. Figures 8-14 provide increasing detail regarding the suction assembly of the present invention, including step-wise views of the various suctioning and clearing modes of operating the suction assembly. Figures 15-17E provide increasing detail regarding the filling dispenser aspects of the present invention. Figures 18A-20C provide various views of alternative applicator tips which are believed to be useful in performing particular types of medical procedures with the overall medical fluid applicator variation of the present invention.

Referring to a general overview of the device as shown in Figures 1-2C, medical fluid applicator assembly 1 is illustrated in Figure 1 during one mode of operation as a tissue adhesive or sealant applicator. Applicator tip 10 of the device is shown with an arrow as it is withdrawn across a tissue surface not shown such that the tip suction aperture 12, which is coupled to an external vacuum source (not shown), via a vacuum connector 13, leads the tip dispensing aperture 14, which is coupled to a tissue adhesive source, across the tissue surface. In this manner, vacuum applied to the tip suction aperture 12 aspirates fluids from the tissue to thereby prepare the tissue for fluid application. As the tip dispensing aperture 14 translates across the tissue surface immediately behind tip suction aperture 12, a trail of tissue adhesive 16 is dispensed onto the prepared tissue.

It is believed that a close proximity in time between tissue preparation and fluid application has a particularly useful application in dispensing tissue adhesives onto tissue surfaces in wound closure procedures. It is further believed that the sensitive ability to select levels of applied suction, as provided by the present suctioning device invention, beneficially allows for desired control in preparing the tissue, aspirating overflow of dispensed fluid, and manipulating tissue to proximate the dispensing tip. As would be apparent to one of ordinary skill, the remaining detailed disclosure below describes additional operating features of the overall medical fluid applicator embodiment, as well as additional specific features of the novel suctioning assembly of the current invention, in addition to the features shown in Figure 1 which provide for tissue preparation contemporaneous with fluid application.

The applicator is ergonomically designed to be conveniently held in one hand and is provided with a

suction control button 15 and a fluid dispensing actuator 17 conveniently located for separate or simultaneous operation by one hand of the user, or even, with some practice, to be simultaneously operated by the thumb alone. Thus the device can be used to simultaneously suction prepare a surface and deposit a trail of dispensed fluid such as a tissue sealant, in a single pass.

In the description herein, it is assumed that the external vacuum source is capable of providing a constant negative air pressure with unlimited flow capacity, which is substantially unaffected by operation of the suction applicator of the invention.

In an alternative aspect of the invention, where it is desired to controllably dispense a variable air flow, suction connector 13 may instead be connected to a source of pressurized air, enabling an operator to dispense a desired air stream from applicator tip 12 in an equivalent manner to the application of suction, which is described herein in detail.

As shown in Figure 3, the inner workings of medical fluid applicator 1 in one preferred variation are divided between supply device portion 2 and applicator portion 3 which is removably engageable to supply device portion 2. As is apparent to one of ordinary skill by reference to Figure 3, when applicator portion 3 and supply device portion 2 are engaged, proximal and distal portions of a fluid dispensing pathway 5, a suction pathway 7 and a clearing pathway 8 are coupled, respectively. These pathways thereafter allow for fluid dispensing, applied suction, and clearing of the applicator tip, respectively, as will be apparent to one of ordinary skill from the more detailed description provided below.

The various components of the dispenser assembly to be combined with the current suctioning assembly of the current invention are generally shown in Figures 3-7. In this variation, the dispenser assembly includes an overall dispensing pathway 5, the proximal portions of which being shown in detail in Figures 4A-C, as well as an actuating assembly 100 for dispensing fluid through that pathway, shown in detail in Figures 5-7.

Regarding the components of the fluid dispensing pathway 5 as shown various throughout Figures 3-4C, proximal portions of that pathway within the supply device portion are shown in Figures 4A-B to include two reservoirs 52,54 which communicate with two supply conduits 56,58, respectively. Supply conduits 56,58 extend distally therefrom and terminate distally in two supply ports 60,62, respectively.

It is to be further appreciated by one of ordinary skill that the reservoirs of the fluid dispensing pathway can take a number of forms as long as they are adapted to contain the desired fluid, are pressurizable by an

engaged actuating mechanism, and are coupled to a dispensing conduit for distal flow. In the embodiment shown throughout the figures, the reservoirs are tubular chambers which are pressurizable as syringes by means of slideably engaged plungers. In an alternative embodiment not shown, the reservoir may instead comprise a flexible bulb or tube that may be directly compressed, which compression may also be accomplished by means of a plunger. Any suitable arrangement whereby the application of pressure to the reservoir attached to the dispensing means will result in application of the contained fluid is acceptable.

Distal portions of fluid dispensing pathway 5 located within applicator portion 3 are shown in shadow in Figure 4C. Here, dispensing conduit 70 has a branched portion 80 and a mixing portion 90 that resides in part within applicator tip 10. Branched portion 80 includes two branch conduits 82,84 which terminate proximally in proximal dispensing ports 86,88, respectively. The branch conduits 82,84 merge at the proximal end of mixing portion 92, which extends distally therefrom through applicator tip 10 where it terminates at tip dispensing aperture 14.

Therefore, it should be apparent to one of ordinary skill by reference to Figures 3-4C that fluidly coupling supply ports 60,62 and dispensing ports 86,88 at the supply device/applicator portion interface creates interface fluid dispensing pathway 5 which includes reservoirs 52,54, supply conduits 56,58, branch conduits 82,84, and mixing conduit 92.

Actuating assembly 100 is also shown in overview fashion in Figure 3, with more detailed reference to the components thereof provided with reference to Figures 5-7. In overview, actuating assembly 100 includes trigger 105 which is mechanically coupled to two parallel plungers 142,144, which are in-turn coupled to fluid dispensing pathway 5 via slideably engagement within reservoirs 52,54, respectively. By manually depressing trigger 105, plungers 142,144 advance within reservoirs 52,54 to thereby pressurize the fluids and dispense them distally therefrom and through the remaining portions of fluid dispensing pathway 5.

Referring to the detail of actuating assembly 100 shown in Figures 5-7, trigger 105 is coupled to pawl 120 via lever arm 110. Spring 115 is further shown with one end engaged with lever arm 110 and the other end engaged with pawl 120. In this arrangement, both trigger 105 and pawl 120 have a spring bias such that trigger 105 has a first resting position and pawl 120 has a reward resting position. Pawl 120 is further shown in Figure 5 to include a hook 122 which has a flat distal face 124 and a radiused proximal face 126. Hook 122 functions to engage rack 120 with rack 130.

Rack 130 is further shown in Figures 5-6 to include a rack face having a plurality of teeth 132 which border either side of a longitudinal groove 133 extending along that rack face. These teeth 132 are

longitudinally spaced with a gap 134 which is adapted to receive hook 122, each tooth including a radiused distal face 136 and a flat proximal face 138. At the proximal end of rack 130, engaging arm 139 is shown as a branched arm extending downwardly to engage at least one of plungers 142,144.

The actuating assembly shown and described further includes a decoupling mechanism, which is shown in-part in Figures 5 and 6 not included in the view of the dispensing assembly shown in Figure 3. A narrow decoupling arm is shown in Figure 5 as a longitudinal extension of tab 152 and includes a plurality of sloped cam surfaces 131 which resides within rack 130 and which rest on a bottom face of the rack in confronting engagement with a plurality of sloped decoupling surfaces, such as sloped decoupling surface 135. The decoupling arm may be adjusted upwardly through the upper face of the rack through longitudinal groove 133 by moving the decoupling arm proximally within the rack to allow the arm to be lifted by the sloped decoupling surfaces. The decoupling arm is further limited in its longitudinal motion within the rack such that the tab engaged to the arm may be used to withdraw the rack, and therefore the plungers engaged therewith, proximally within the outer casing of the device housing.

Each of plungers 142,144 of actuating assembly 100 Figure 5 includes a proximal shaft and a distal head, as is shown by example at proximal shaft 146 and distal head 148 in Figure 7. Plungers 142,144 include a plurality of splines 147 which are spaced in order to receive and mechanically engage engaging arm 139 therebetween. Distal head 148 is configured of geometry and material to slideably but frictionally engage the interior wall of one of the fluid reservoirs. As such, distal head 148 is adapted to slide within the corresponding reservoir during forward advancement of the plunger in order to pressurize the fluid within that reservoir. Yet, distal head 148 is also adapted to be frictionally in contact with the reservoir's inner bore in order to prevent backflow of the pressurized fluid. In one variation, an elastomeric member such as an O-ring may be included, such as O-ring 149 shown in Figures 5 and 7.

Closely integrated with the operation of actuating assembly 100 are visual volume indicator 150 and audible volume indicator 200, as shown in overview fashion in Figure 3.

Visual volume indicator 150 is shown in Figure 3 and also in Figure 5 to include a tab 152 which rests above the housing of the device which is shown as outer casing 20. Tab 152 is coupled to lower arm 154 that extends downwardly through longitudinal groove 24 Figure 3 in the upper surface of outer casing 20 and is further engaged to rack 130. Visual graduations 156 are provided on the upper surface of outer casing 20, which graduations correspond the relative position of tab 152 to known volumes of fluid delivery.

The mechanism of an audible volume indicator 200 is herein described also by reference to Figure 3, as well as to Figures 5 and 6. Audible volume indicator 200 includes a striker 210 which is actuated by teeth 132 to emit audible tones of varying pitch or loudness as fluid is cumulatively dispensed over a range of discrete, incremental volumes of fluid. Striker 210 is secured to the interior of outer casing 20 with fixed positioning relative to the longitudinal motion of rack 130 and includes a plurality of striker arms 220 Figure 3 which are spaced laterally across the face of rack 130.

Teeth 132 are further shown to include various regions along the longitudinal axis of rack 130, such as regions 137,139 shown in Figure 6. Each region has a unique lateral position on the rack relative to the adjacent regions and is thereby adapted to strike a unique combination of laterally spaced striker arms 220 when advanced distally across striker 210, as would be apparent to one of ordinary skill. The distance between the leading edges of each region generally corresponds to an incremental distance of longitudinal travel for rack 130 relative to striker 210 with fixed relative positioning. This incremental distance of travel for rack 130 further corresponds to a predetermined, incremental volume of actuated fluid delivery. Therefore, this arrangement allows for a unique tone to be emitted from a unique combination of striker arms 220 at each discrete, incremental volume of fluid delivered. Therefore the cumulative volume of fluid delivered is recognized by the unique loudness or pitch of emitted tone since the extent of forward positioning of rack 130 within outer casing 20 corresponds with a specific regions of teeth 132 that strike unique combinations of striker arms 220.

It is to be further understood by one of ordinary skill that the particular mechanism disclosed for varying the pitch or loudness of audible signals should not limit the breadth of scope for the present invention. For example, in the embodiment shown, striker arms 220 are shown to be relatively uniform in size and geometry and the various regions of teeth 132 are shown to simply vary in length while sharing common central regions which may engage some of striker arms 220. In this arrangement, it is the number of actuated striker arms 220 which varies with the tooth regions, which corresponds to a change in the loudness of the tone emitted for each region. However, other arrangements may also be suitable. In one alternative embodiment not shown, the geometry or material of the striker arms may vary along the striker, wherein each unique arm may emit a uniquely pitched tone. In combination, the teeth regions may be as shown in the figures with common striking portions, or may be shifted to only actuate audible signals from entirely unique sets of teeth, as would be apparent to one of ordinary skill.

Moreover, other mechanisms than the rack teeth mechanism shown and described may be suitable for varying the tone or pitch of an audible signal as fluid delivery is actuated. For example, the teeth may be fixed within the casing of the device, with the striker translating across those teeth as an actuator delivers

fluids. Alternatively, the teeth might be positioned along a helical path of a screw, the striker being adapted to engage that path and thereby actuated for tone emission by the teeth there.

Still further, other mechanisms than the shown teeth/striker mechanism may be acceptable, such as an optical or electronic reader which observes changing indicia of actuated fluid delivery and which is thereby coupled to an electronically or electrooptically actuated audible signaling means, as may be apparent to one of ordinary skill. In any case, any variation which audibly emits signals as indicia of cumulative volume of fluid delivery should be considered as a part of the current invention.

The operation of the dispenser assembly used with the current invention is also shown in two modes in Figure 5, wherein actuating assembly 100 is shown actuated through one full range of motion or "stroke" of actuating trigger 105. As is evident to one of ordinary skill by reference to Figure 5, depressing trigger 105 through one stroke actuates forward movement of pawl 120 from a reward resting position to a forward actuated position shown in dashed line. This motion is achieved by flat distal face 124 of hook 122 confronting the flat proximal face 138 of teeth 132 such that the forward movement of pawl 120 pulls rack 130 forward. As rack 130 pulls forward, plungers 142,144 engaged to rack 130 are also actuated to move forward into the bore of the fluid reservoirs, as is shown at fluid reservoir 52. As the fluid in the reservoirs are pressurized with the forward motion of plungers 142,144, that fluid is dispensed distally through the fluid dispensing pathway, originating from the reservoirs and flowing from the supply device portion and into the applicator portion through supply ports.

The dispenser assembly shown and described for the current invention is filled or refilled after completion of fluid dispensing as follows. Filling is initiated with the rack and the plungers in a fully forward and actuated position. The tab engaged to the rack and to the narrow decoupling arm also has a forward position. The device is coupled to a filling dispenser, such as the novel filling dispenser shown and described with reference to Figures 15-17E below. The tab is then manually withdrawn through the longitudinal groove in the outer casing of the supply device. By doing so, the cam surfaces on the bottom face of the disengaging arm slide across the decoupling cam surfaces on the bottom face of the rack until reaching the stop within the rack, thereby lifting the disengaging arm upwardly through the longitudinal groove in the upper face of the rack to lift the hook of the pawl and disengaging it from the teeth on the rack surface. Continued proximal movement of the tab relative to the outer casing of the device also pulls the plungers and the rack rearwardly to create a vacuum to fill the reservoirs and to also reposition the rack proximally so the hook on the pawl returns to the front part of the rack.

The spring-biased resting position of trigger 105 further corresponds to a rearward or proximal position

for pawl 120 relative to the longitudinal axis of outer casing 20. When the trigger 105 is released, spring 115 restores the trigger and also the pawl to their original position, while the striker remains in its advanced position along the regions of the teeth on the forward actuated rack. Moreover, the spring-bias and mechanical constraints on the motion of lever arm 110 and pawl 120 within outer casing 20 also limit the range of available motion for trigger 105 from the spring-biased resting position to a fully actuated position, thereby defining the full "stroke" range. The combined features of the overall actuating assembly are adapted such that the available "stroke" range of actuated motion corresponds to a predetermined incremental volume of fluid delivery actuated from the fluid reservoir.

Moving to the suction assembly of the current invention, Figure 3 provides an overview of the overall suction assembly, while Figures 5 and 8-12C provide increasingly more detail of the components and mechanisms of operation thereof.

The proximal portions of the suction assembly located within supply device portion 2 are shown in Figure 5 to include a vacuum conduit 250 which is selectively coupled to vacuum coupling tubes 256,257 by vacuum manifold 300. The distal portions of the suction assembly located within applicator portion are shown in Figure 8 and include a suction conduit 260, a clearing conduit 270. Comparing the overall device assembly shown in Figure 8 with the removed view of supply device portion 2 and applicator portion 3 in Figure 3, it should be apparent to one of ordinary skill that clearing conduit 270 is formed by coupling and aligning supply device suction tube 256 with applicator suction port 258, and similarly coupling and aligning supply device clearing tube 257 with applicator suction port 259 Figure 3 to form one contiguous channel between the valve housing and the mixing portion of the dispensing conduit.

Figures 11A-D and 14A-B further show a shuttle valve 350 which is further included in the distal portion of the suction assembly for adjusting applied vacuum between the suction conduit 260 and the clearing conduit 270. As will be disclosed in further detail below, the valve manifold 300 operates to adjust the proportions of applied vacuum from the vacuum conduit 250 to either the suction conduit 260, when suction at for tissue preparation prior to dispensing, or to the clearing conduit 270, when suction is desirably used to clear coagulated tissue adhesive proximally from the mixing portion 90 of dispensing conduit 70.

The operable features of valve manifold 300 are shown in Figure 8, and include valve housing 301 which houses valve stem 310 in moveable engagement. Valve housing 301 is shown in Figure 8 to form an elongate bore having an open top in communication with atmospheric pressure and which functions as a vent port 302. Furthermore, the wall forming the inner bore of valve housing 301 further includes a

suction port 304 and a clearing port 305 on the distal side of valve housing 301. Vacuum port 303 communicates with vacuum conduit 250, while suction port 304 and clearing port 305 communicate with vacuum coupling tubes 256,257, respectively.

Valve stem 310 is shown variously in Figures 3, 5, and 8, and in more detail in Figures 9A-D, and generally includes a valve chamber 311, a vacuum aperture 312, a suction aperture 314, a clearing aperture 316, and a vent aperture 318, which apertures are shown in detail in Figures 9A-D. Valve stem 310 is generally an elongate tubular member which has an outer diameter adapted to frictionally engage the inner surface of valve housing 301Figure 8. Valve stem 310 is also slidable within valve housing 301, however, and is thereby adjustable between various positions along a predetermined range of motion. According to the embodiment shown throughout the figures, valve stem 310 has a vertical range of motion within valve housing 301 in order to adjust the relative positioning of the various valve apertures for selective registry with the various ports in the valve housing, as will again become more apparent with reference to Figures 12A-14B below. This range of motion is in part limited by the spring which also gives the valve stem a spring-bias in the upward resting position where there is no applied suction.

More detailed description of the various valve apertures and parts as shown in Figures 8 and 9A-E is as follows. Vacuum aperture 312 includes an open bottom of valve stem 310 and also an elongate open slot on the proximal side of valve stem 310. Suction port 314 and a clearing port 316 which are positioned at particular respective positions along a common vertical plane of valve stem 310. In addition, valve stem 310 further includes an open vent aperture 318 which selectively communicates exteriorly of valve chamber by manually covering or uncovering that opening.

In the design of valve stem 310 and its apertures as shown in Figures 9A-E, suction aperture 314 and clearing aperture 316 have similar shapes that are inversely oriented along the direction of movement of valve stem 310. As may be seen in Figure 9E, each aperture 314 and 316 comprises a curved, non-circular, elongated opening having an axis of symmetry "L" aligned with the longitudinal axis of valve stem 310,a wide transverse dimension "W" a narrow transverse dimension "S", all referenced in dashed lines in Figure 9E, for clearing aperture 316. The shape of apertures 314 and 316 may described as a "tear-drop" or a "diminished elliptical" shape. The inverse relative orientations of apertures 314 and 316 means that, during a downward vertical motion of valve stem 310, for suction aperture 314, the short dimension "S" leads the wide dimension "W", as suction aperture 314 moves into registration with suction port 304 while, for clearing aperture 316 the wide dimension "W" leads the short dimension "S"as aperture 316 moves downwardly into valve stem 301 (see Figs. 31A-13B). This construction and arrangement of apertures 314 and 316, in relation to vent port 302 and suction port 304 is particularly

advantageous when clearing aperture 316 functions as a vent in a venturi-like role for controlling the level of suction applied to suction conduit 270, as will be described further below with reference to Figures 13A-B.

A valve actuator 345 is further shown in Figures 3, 5, and 8, and in further detail in Figures 10A-D. Valve actuator 345 can be considered to be a part of the overall assembly for valve manifold 300, as well as for a shuttle valve used in a further variation of the present invention, as will be developed below. Valve actuator 345 is generally a button which has a button bore 346 that is adapted to fit over valve stem 310 such that actuator vent aperture 347, which is provided at the top surface of valve actuator 345, is adapted to align with vent aperture 318 of valve stem 310 when engaged to the top of the valve stem. Near the bottom region of valve actuator 345 is a cam actuator surface 348 which includes at least one stop, such as that shown at stop 349. Cam actuator surface 348 is adapted to engage a cam surface of a shuttle valve when valve manifold 300 is adjusted toward downward position within valve housing 301 in order to actuate movement of the shuttle valve to initiate a suction clearing operation, which will be developed below with reference to Figures 14A-B.

Figures 11A-D show shuttle valve 350 which is adapted to be actuated by valve actuator 345 Figures 10A-D for use in a clearing mode of operating the suctioning assembly of the current invention in the preferred medical fluid applicator design. Shuttle valve 350 functions to selectively couple the mixing conduit portion of the dispensing conduit either to the branched portion for dispensing fluids or to the clearing conduit for retrogradedly clearing clogged adhesive from the mixing conduit.

Shuttle valve 350 is shown in Figures 11A-D to include a body 352 which includes a dispensing valve portion 360, a clearing valve portion 370, and a proximal portion having a cam surface 380. Dispensing valve portion 360 includes two vertical splines 362,363 which are parallel to the longitudinal axis dashed line of shuttle valve 350. Vertical splines 362,363 have dispensing conduit apertures 364,365, respectively, which extend therethrough in a transverse horizontal plane relative to the longitudinal axis. Vertical splines 362,363 further have closed regions which are adjacent the corresponding dispensing conduit apertures, such as is shown in Figure 11B at closed region 366 for vertical spline 362 and in Figure 11C at closed region 367 for vertical spline 363. Clearing valve portion 370 includes a horizontal face 372 which extends between vertical splines 362,364 and which further includes a clearing conduit aperture 374 therethrough in an angled vertical plane relative to the longitudinal axis. At least one seal member 390 is further shown to be disposed upon the outer surface of the respective valve portions, which seal member is preferably an elastomeric or compressible material, such as an elastomeric polymer or a rubber.

The means for actuating shuttle valve 350 in order to operate the suction shuttling in the clearing variation of the present invention is further shown in Figures 11B-C. Cam surface 380 is disposed on an angled vertical plane relative to the longitudinal axis of shuttle valve 350. In this orientation, cam surface 380 is adapted to slideably engage cam actuator surface 348, as is further shown in Figure 11C. As the valve actuator 345 is depressed in a downward motion, cam actuator surface 348 contacts cam surface 380. Further downward motion of valve actuator 345 forces shuttle valve 350 to advance transversely to the motion of valve actuator 345 and in the longitudinal plane of shuttle valve 345. This is because shuttle valve 345 is restricted from moving within the applicator tip in all directions except longitudinally. The angled interaction between cam actuator surface 348 and cam surface 380 provides the longitudinal component of normal force therebetween to actuate the longitudinal shuttling motion.

Further included in the shuttle valve mechanism of the present invention is a spring bias on the shuttle valve in a rearward resting position, such as by use of a spring which is engaged to the shuttle valve and also to the interior of the applicator portion of the device housing not shown. The forward actuated movement of the shuttle valve by operation of the actuator works against that spring bias such that upon releasing the actuator the shuttle valve returns to the rearward position.

The operation of the valving components of the present suctioning invention, including the valve manifold and the shuttle valve in the clearing variation, is shown in various modes of operation throughout Figures 12A-14B. Figures 12A-12C show the relationship of the various positioning of valve manifold 300 in the creation of different pathways for suction through the various available conduits. Figures 13A-B schematically shown the positioning of valve manifold 300 and shuttle valve 350 during different modes of venting and suctioning operations at the applicator tip. Figures 14A- B show different positions for valve manifold 300 and shuttle valve 350 in the creation of an alternative clearing pathway for applied suction through the clearing conduit to clear the mixing portion of the dispensing conduit.

Figure 12A shows valve manifold 300 in a venting position such that a vent pathway 4bolded arrows is created and there is no applied suction to suction conduit 260 or clearing conduit 270. In this position, vacuum conduit 250 communicates with valve chamber 311 which is exposed only to atmospheric pressure through vent aperture 318 and the coupling between clearing aperture 316 and vent port 302 above valve housing 301. In this case, clearing aperture 316 functions as another vent aperture. As is apparent in Figure 12A, this venting position is the resting position for valve manifold due to a spring bias to that position created by spring 330 as stop 349 engage portions of interior surface of outer casing 20.

Figure 12B shows valve manifold 300 in a first suction position such that a suction pathway 6 is created

by registering suction aperture 314 with suction port 304. In this position, vacuum conduit 250 communicates with suction conduit 260 to apply vacuum pressure to that suction conduit in the suction pathway 6. Further, clearing aperture 316 is closed within valve housing 301 and a user's thumb functions to close vent aperture 318 during downward actuation of the valve manifold 300. By maintaining these apertures in a closed condition, the suction pathway 6 is isolated to achieve full vacuum at the applicator tip.

Figure 12C shows valve manifold 300 is a second clearing position such that a clearing pathway 7 is created by registering clearing aperture 316 with clearing port 305. In this position, vacuum conduit 250 communicates with clearing conduit 270 to apply vacuum pressure to that clearing conduit through clearing pathway 7. The completion of clearing pathway 7, however, is intended to include mixing conduit 92, in order to achieve the intended operation of clearing clogging obstructions from that conduit. This coupling to the dispensing conduit is achieved through the actuation of the shuttle valve, as will be described in more detail with reference to Figures 14A-B.

As shown in Figure 12C, the clearing conduit 270 is coupled to the proximal end of the mixing conduit 92 such that a continuous taper is created with distally reducing inner diameter between those conduits. It is believed that this tapered geometry may enhance the retrograde passing of contents within mixing conduit 92 due to applied suction, particularly when such contents are coagulated or cured tissue adhesive or sealant. Furthermore, it is believed that such taper should preferably be a gradual one. It has been observed that, where too drastic a taper is provided in the clearing pathway, initial proximal movement of the targeted coagulum creates a shunting pathway around the coagulum. This shunting pathway may significantly diminish the proportion of applied vacuum pressure onto the coagulum for withdrawal. However, some taper may be required for a particular fluid matrix to be cleared, due to the frictional dynamics of withdrawing the coagulum through the pathway. Thus, while a gradual taper such as that shown may be sufficient for many fluid delivery applications, other tapered geometries may be more preferable for a particular fluid application, as would be apparent to one of ordinary skill.

The operation of valve manifold 300 is shown schematically in Figures 13A-B in operating the suctioning invention to apply selected, varied levels of suction to suction conduit 260 . In particular, the relationship between clearing aperture for venting purposes and suction aperture are shown in achieving different selected levels of applied suction at suction conduit 260.

Figure 13A shows the valve manifold with valve stem 310 in the resting or venting position, similar to that shown in Figure 12A. There is no suction at suction port 304, nor at clearing port 305 because

neither of the respective suction or clearing apertures 314,316 is aligned therewith, and instead the wall of valve stem 310 blocks communication through those ports. Venting is achieved in this position either through vent aperture 318 or through clearing aperture 316, which communicates with atmospheric pressure above the top of valve housing 301 through vent port 302, or through both bolded arrows. In one mode during initial actuation of valve manifold 300 to various actuated positions, vent aperture 318 is manually blocked and full venting is achieved through clearing aperture 316.

Figure 13B shows the valve manifold after actuation of valve stem 310 to move it to a suctioning position within the valve housing, which position is substantially downward of the position shown in Figure 13A , but not yet at the end of the travel of valve stem 310. It is to be understood by one of ordinary skill that, as valve stem 310 moves downwardly between these two positions, suction aperture 314 and clearing aperture 316 translate across and register at least in part with suction port 304 and vent port 302, respectively, to provide a variable suction throat and a variable venting throat, respectively. It is to be further understood that, during this downward motion of valve stem 310, suction aperture 314 has an increasing cross-sectional area which registers with suction port 304, going from its short axis to its wide axis. Simultaneously, clearing aperture 316 instead has a decreasing cross-sectional area which communicates with atmospheric venting through vent port 302 as its wide axis leads its short axis downwardly into valve housing 301. Thus, the suction throat is expanding while the venting throat is contracting.

In this embodiment suction ports 304 and 305 are contemplated as being circular openings essentially corresponding in shape and size with the internal cross-sections of suction and clearing tubes 256 and 257 respectively, and thence with suction conduits 260 and 270. However, if desired, for suction control or other purposes, ports 304 and 305 could have a different shape, e.g. rectangular, (or dimension) from the internal cross-sections of suction conduits 260 and 270 with suction and clearing tubes 256 and 257, providing a transition in section from one to the other. Such rectangular or other shape will cooperate with the teardrop or other shape of ports 314 and 316 to determine the configuration and area of the variable suction throat (defined by ports 304 and 314) and of a variable clearing throat (defined by ports 305 and 316), as will be apparent to those skilled in the art or may be determined without undue experimentation. In most cases, when clearing, the operator will desire to apply full suction as quickly as possible. However, scope for various degrees of adjustment of the intensity of the clearing suction is provided by suitable selection of the configuration of ports 305 and 316, provided that due regard is paid to the extent to which the configuration of port 316 affects the venting characteristics of the applicator.

Further to the suction valving mechanism as shown in operation in Figures 13A-B, a combination of

"venturi"-type and "trumpet"-type valve mechanisms are used to achieve controlled suction at suction conduit 260. The term "venturi"-type valve is herein intended to mean a valve mechanism that adjusts applied suction at a working pathway where applied suction is intended by adjusting the degree of parallel venting through at least one vent pathway. The term "trumpet"-type valve is herein intended to mean a valve mechanism which adjusts the applied suction at the working pathway by selectively occluding or opening the cross section of the conduit directly in the working pathway. Clearing aperture 316, when translated across the open vent port 302 and downwardly into valve housing 301, functions as an adjustable venturi-type valve to shunt applied vacuum in a selected manner away from another open suction pathway through suction conduit 260. Suction aperture 314, when translated across suction port 304, functions as a trumpet-type valve to directly adjust the resistance to applied vacuum to suction conduit 260.

In this combination suction valving mechanism of the present invention, it has been beneficially observed that a controllable range of vacuum pressures may be achieved at suction conduit 260, and that a zero vacuum state can also be achieved at that conduit. It is believed that the venturi valve mechanism arises from operating clearing aperture 316 as a vent, and together with the simultaneous adjusting of that vent with the adjusting of a trumpet valve component through the suction aperture operation, provides a controllable range of applied pressures. It is further believed that the inverse orientation of short and wide cross-sectional areas of the venturi clearing aperture and trumpet suction aperture valving apertures, in relation to the direction of travel during the combination valving function, further enhances the ability to control the applied suction to selected levels. In addition, the trumpet valve component arising from the operation of suction aperture 314 makes the completely closed, zero vacuum condition possible.

It is further contemplated that, while the inversely oriented tear-drop or diminished ellipse shapes for the suction and clearing apertures are considered particularly useful in controlling selected levels of applied suction to a working suction conduit, the invention is not so limited to that particular arrangement of aperture shapes. Various shapes other than the "tear-dropped" shape described and shown for suction and clearing apertures 314,316 may be acceptable in various modes of operating the assembly. For example, circular apertures may be used, or one of the suction or clearing apertures may be circular and the other may be a different shaped, such as the tear-drop shape or diminished ellipse.

More specifically regarding the diminished elliptical shapes of the particular embodiments, the ratio of the elongate axis length to the change in cross-sectional area between short and wide axes along that elongate axis may be adapted for a particular intended use. For example, it is believed that a longer elongate axis, with a more gradual change in cross-sectional area from the short axis to the wide axis of the shape, may

provide for a longer length of actuating travel between selected levels of suction, and therefore may result in more sensitive control of minute changes in suction level.

Expressed qualitatively, as suction aperture 314 begins to register with suction port 304, low level suction is applied to suction conduit 260 and the suction throat defined between suction port 304 and suction aperture 314 is gradually enlarging. If valve manifold 300 remained fully vented any suction delivery to conduit 260 would be minimal. Therefore, the shape of clearing aperture 316 is selected so that the venting throat it defines with valve housing 301 diminishes rapidly at this point in the downward travel of valve manifold 300 to quickly reduce the degree of venting.

At this point, although it will quickly diminish as valve stem 310 moves downward, substantial venting is still desirable to provide a mode of gentle aspiration, for example, for removal of fluids or debris from a delicate tissue surface, or to permit careful manipulation of delicate tissue, and to prevent grabbing of the tissue. It will be appreciated that although the suction regulation throat defined by aperture 314 and port 304 may be quite small, once suction conduit 260 becomes occluded, for example by a flap of tissue, were there no venting, the full (negative) pressure of the suction source would be applied to the occluding flap, holding it securely to the mouth of suction conduit 260, and possibly creating problems for a surgeon or other user. Such problems are greatly mitigated by means of the invention which enables automatic balancing of the applied suction with appropriate levels of venting by suitable selection of valve port characteristics, as described herein. Should tissue holding problems nevertheless still arise, they are easily resolved by manual unblocking vent 318.

To provide effective suction management, it is important to consider not only the delivered negative pressure which, for a constant pressure vacuum source, will be determined by the relative proportions of the suction throat to the venting throat, but also the sustainable flow rate, which will be determined by the magnitude of the suction throat. It is also important to consider the likelihood and intensity of undesired tissue holding which will largely be determined by the magnitude of the venting throat.

With these considerations in mind it will be understood that the shapes of ports 314 and 316 can be varied to provide desired combinations of operating characteristics. It will also be understood that the invention advantageously provides for operation of both a venting valve and a suction control valve with a single action by employing a compound valve but that separate valves could be employed. Such separate venting and suction control valves could be coupled together mechanically, by a suitable linkage, or ergonomically by suitably positioning two controls for simultaneous operation. In such a separated configuration, various combinations of valve member and valve housing ports will be possible. However

in the particularly advantageous embodiment of the invention shown in the drawings, employing a compound valve, it is desirable to locate the openings with a complex shape on the moving valve stem 310 and to employ simple circular or rectangular shapes for the registering openings in valve housing 301.

In moving between the positions shown in Figures 13A and 13B, valve stem 310 passes through a useful intermediate position where ports 304 and 314 substantially overlap so that the suction throat is substantially open, while port 316 is still substantially clear of the valve housing 301 so that substantial venting is also available. This position provides a moderate level of suction with a good flow rate for material removal, and with significant venting to control tissue holding. In all positions between full venting and full suction the illustrated suction control embodiment of the invention provides good response characteristics and a good feel so that small movements of valve stem 310 result in detectable changes in the applied suction. In the described intermediate position, the applicator can be quickly and easily adjusted either to full suction or to gentle aspiration.

If desired, although not shown, means for example detent means or friction means can be provided temporarily to locate valve stem 310 depressed into one or another desired operative position, for example, gentle aspiration, intermediate suction and full suction, to enable the operator to remove their thumb or finger from valve manifold 300 and operator trigger 100 to apply adhesive, or perform some other task. Such detent means should be readily releasable, for example, by slight additional pressure. Optional vent aperture 318 is preferably not employed with such detent means, but means could be provided to occlude it, if necessary. If friction means are employed to locate valve stem 310 in selected positions along its travel, an alternative return means to bias spring 330 is preferably utilized to return valve stem 310 to ts rest position, for example a manully operated lever or push rod.

Table 1 below summarizes the various juxtapositions of the several ports and apertures that occur as valve stem 310 is depressed.

Table 1: Port Configurations at Various Positions of Valve Stem 310

Illustration:	Fig. 13A	Between Figs. 13A & 13B	Fig. 13B & Fig. 14A	Fig. 14B
Valve stem 310	Not depressed	Partially depressed	Abt. half depressed	Fully depressed
Function:	Resting/Vented	Apply moderate suction.	Apply strong suction.	Clearing

Valve h'sing 301:				
Suction port 304	closed	partially open	open	closed
Clear port 305	closed	closed	closed	open
Valve stem 310:				
Vacuum ap. 312	open	open	open	open
Suction ap. 314	closed	open	open	closed
Clearing ap. 316	fully vented	nearly closed	nearly closed	open
Vent aperture 318	open	manually closed	manually closed	manually closed
Result:	Suction source vents through 316.	Suction and venting..	Nearly full suction at conduit 260.	Full suction at conduit 270.

Further to the shuttling operation of adjusting applied suction from selected conduits, Figures 13A-B also show the distal portions of shuttle valve 350 as it interacts and couples with the dispensing and suction assemblies. Each of branch conduits 82,84 and clearing conduit 270 includes a slotted region, such as slotted region 83 in branch conduit 82 or slotted region 271 in clearing pathway 270, through which the respectively engaged valve portion may be slideably received. Dispensing valve portion 360 and clearing valve portion 370 are engaged within the slotted regions of dispensing conduit 70 and clearing conduit 270, respectively. Actuation of the shuttle valve components through these slotted regions for the purpose of selecting operable fluid pathways in a clearing function is further discussed with reference to Figures 14A-B below.

In actuating valve manifold 300 from the vent position to the first suction position or somewhere therebetween as shown in Figures 13A-B, shuttle valve 350 remains in a resting reward position within the applicator portion. This is because, over the range of motion between the two respective valve manifold positions, the cam actuating surface on the valve actuator has not yet contacted the cam surface of shuttle valve 350 to actuate motion thereto not shown. Further to this rearward resting position shown for shuttle valve 350, actuator dispensing apertures such as actuating dispensing aperture 364 on vertical spline 362 are aligned and registered with the interior lumens of each branch conduits in their respective slotted regions, which alignment allows for fluid dispensing. However, actuator clearing aperture 374 on clearing valve portion 370 is out of alignment with the interior lumen of clearing conduit 270 in the slotted region thereof, and instead closed portion 376 of valve clearing portion 370 is aligned in that slotted region to block flow therethrough. Further detail as to the mechanism of actuating the valving mechanisms of shuttle valve 350 are further developed with respect to Figures 14A-B.

Figures 14A-B show schematic views of the role of valve manifold 300 and shuttle valve 350 in the clearing function of the suction assembly of the current invention. Figure 14A shows the valve manifold positioning and applicator portion during the operation of dispensing a mixed fluid, while Figure 14B shows a subsequent operation of clearing mixed fluid and deposited solids from the applicator tip region

to prevent clogging.

Figure 14A provides a schematic view of the valving operation of the device during use it tissue preparation prior to dispensing, as shown in perspective view in Figure 1. Each of two different fluids is shown being dispensed through either branch channel 82 or branch channel 84. Shuttle valve 350 is in the reward resting position to allow the fluids to flow through the dispensing valve portions and mix in mixing conduit 92. The mixture is further shown being dispensed out tip dispensing aperture 14. Simultaneously the fluid delivery just described, valve manifold 300 is shown adjusted to the first suction position (or something close thereto) to allow for suction pathway 6 to couple vacuum pressure to the tip suction aperture 12.

Figure 14B shows the same schematic view of Figure 14A after fluid dispensing and during a clearing operation. Shuttle valve 350 is actuated into a forward actuated position. In this position fluid communication is blocked between vacuum conduit 250 and branch conduits 82,84 via the closed portion 366 of dispensing valve portion 360. Also in this position, communication is opened between vacuum conduit 250 and mixing conduit 92, through clearing conduit 270, via clearing valve aperture 374. The seal members Figures 11A-D on the dispensing valve and clearing valve portions 360,370 allow for slidable engagement within the respective slotted portions of the engaging conduit lumens, yet substantially maintain fluid integrity at those slotted portions and around the engaging valve portions.

Thus, clearing pathway 7 is created in this shuttling operation, and the mixed fluid in mixing conduit 92 is shown in Figure 14B as it is withdrawn due to suction through clearing pathway 270. Furthermore, by blocking communication between the branched portion 80 of dispensing conduit 70 and the mixing conduit 92 of dispensing conduit, contents proximal to the shuttle valve within the fluid dispensing pathway, including that in the supply reservoirs not shown, are isolated from vacuum pressure and also from the contaminating coagulum being withdrawn from mixing conduit 92 in the case of tissue adhesive applications.

It is further contemplated that the shuttle valve of the present invention may take a different form than that specifically described with reference to Figures 11A-D and 13A-14B without departing from the scope of the present invention. For example, rather than the shuttle valve shown and described, the slidable shuttling mechanisms of dispensing valve portion 360 and clearing valve portion 370 through slots in the engaging conduit lumens may be replaced with other types of individual valve mechanisms which may operate separately or in coordination. One example of a suitable alternative may be individual trumpet valve-type mechanisms engaged with each respective conduit lumen to selectively restrict flow

therethrough. Any suitable mechanism which is apparent to one of ordinary skill from this disclosure and which allows for the desired selection of open and closed lumens in the dispensing and clearing conduits during the dispensing and clearing operations described is considered within the scope of the current invention. Therefore, where "shuttle valve" is used throughout this disclosure, it should be apparent that these other suitable valving alternatives are also contemplated.

It is to be further understood with reference to Figures 12A-14B that the ability to open vent aperture 318 to atmospheric pressure at any time by removing the actuating user's finger therefrom contributes a safety feature to the overall design. It is contemplated that, during some uses, the suction in the tip of the device may aggressively engage and hold tissue proximate to that tip. In a case where the valving mechanisms provided with the device may stick in an actuated position, or when very rapid release of suction is desired, opening vent aperture 318 immediately shunts most all of the applied suction out that port to thereby allow for rapid release of engaged tissue at the applicator tip.

In another variation of the current suctioning device invention, supply device portion 2 of the overall combination medical fluid applicator assembly is shown in Figures 15 and 16 during a filling operation using a beneficial design of filling dispenser. Further detail of the beneficial filling dispenser is shown for filling dispenser 400 in Figures 17A-E.

As shown generally in Figures 15 and 16, filling dispenser 400 includes first and second filling reservoirs 410,420 that are separated and isolated by a divider 401. Filling reservoirs 410,420 include dispenser filling ports 414,424, respectively, which are adapted for use in filling the filling reservoirs with the desired fluids to be transferred to the supply device portion of the medical fluid applicator for delivery. In one variation, the filling reservoirs may be provided "pre-loaded" with liquid components, or in some cases dried components, of the desired fluid, in which case dispenser filling ports 412,422 may be used for additives such as catalysts, buffers, or other agents. Filling reservoirs 410,420 further include applicator filling ports 414,424, respectively, which are adapted to couple to supply ports of the supply device via keyed coupling 430.

As shown in overview in Figure 16, keyed coupling 430 is adapted to engage supply device portion 2 such that the fluid reservoirs of the supply device portion are coupled to the applicator filling ports, and thus the filling reservoirs, in a predetermined orientation. In other words, only one, predetermined fluid reservoir of the supply device portion may be coupled to each filling reservoir of the filling dispenser. In the embodiment shown in Figure 16, the actuating assembly is operated in a reverse mode for filling the fluid reservoirs. Tab 152 of the visual volume indicator is also adapted as a filling actuator, which may be

manually withdrawn in the proximal direction to provide suction into the fluid reservoirs of the device and thus fill them with fluids from the coupled filling reservoirs.

Figures 17B depicts one of the filling reservoirs 420 which is filled at least partially with fluid 17, which may for example be one part of a two-part fluid, such as one of two parts which mix to form fluid 16 shown dispensed from medical fluid applicator 1 in Figure 1. The portion of the supply device which couples with the applicator filling ports, which may be the supply ports respectively coupled to the fluid reservoirs as shown in Figure 3, is shown in shadowed view in Figure 17B. Here one supply port of the medical fluid applicator is shown coupled to applicator filling port 424 and is positioned within well 425 at the bottom of the respective filling reservoir 420. In this design, the efficiency in withdrawing a substantial portion of the fluid in the filling reservoirs is enhanced. Figures 17C-E show various views to enhance the understanding of the various features of filling dispenser 400 just described.

In the keyed coupling shown and described, the dispensing characteristics for each fluid reservoir may be specially adapted for the specific type of fluid which is contained in the predetermined filling reservoir to which it will couple. For example, each part of a two-part fluid may be contained in each filling reservoir. The two parts may be intended to mix in a particular ratio, such as in a ratio of one part of one fluid to two parts of the other. In this case, the fluid reservoirs of the supply device may have differing bore cross-sections such that one full actuation stroke constitutes one volumetric unit of fluid delivery from one fluid reservoir, and two volumetric unit of fluid delivery in the other. By keying the coupling between the supply device and the filling dispenser as provided in this variation, the proper fluid may always be filled into each fluid reservoir.

It is to be understood by one of ordinary skill that the present invention is not to be limited to specific types of fluids to be filled in the medical fluid applicator, and particularly in regards to the filling operation provided with the filling dispenser just described. For example, biologic and synthetic tissue adhesives, wound closure sealants, and various pharmacologic agents may be dispensed from the filling dispenser and subsequently applied in medical procedures with the medical fluid applicator of the present invention.

It is, however, believed that the various beneficial dispensing, suctioning, and clearing functions of the present invention present particularly useful benefits in the medical application of delivering of biologic or other adhesives to tissue surfaces. In this regard, "adhesive" is herein used throughout this disclosure to collectively describe substrates which are either useful literally as adhesives for adhering biological tissues, and/or which are useful as sealants or closure substrates used to seal spaces within the body, such

as for wound closure procedures.

More particularly, it is further believed that delivery tissue adhesives or sealants which cure or coagulate relatively rapidly may present a particular need for the clearing feature provided with the current invention and described in detail above. The term "cure" and derivatives thereof is herein used throughout this disclosure to mean any mechanism giving rise to substantive physical change in the substrate which affects its mechanical and fluid flow properties, such as for example "coagulating", "congealing," or "cross-linking" mechanisms. Furthermore, such "quick" curing substrates often come in two-part form which, upon mixing, activates a rapid curing response.

Examples of such tissue adhesives or sealants the delivery of which may be enhanced by use of the clearing function just described are many. For example, several composite tissue adhesives "CTA" have been described which may require retrograde clearing intermittently during a fluid delivery procedure. One example of a suitable CTA for use with the present delivery invention may be fibrin-based composites such as fibrin-collagen composites. Furthermore, polyethylene glycol PEG cross-linked composites, such as PEG-collagen or PEG-hyaluronic acid composites may be suitable. A further example of a two-part tissue adhesive is disclosed in EP 592 242 to Edwardson et al, wherein a fibrin monomer is coadministered with a buffer solution in a tissue sealant operation.

Other examples of suitable substrates for delivery with the current invention include certain classes of protein polymers which have biologic adhesive qualities, such as an amplified fibrinogen-like protein which is activated either by chemical cross-linking, such as with glutaraldehyde, or by enzymatic cross-linking such as with thrombin or Factor XIIA. Furthermore, plain plasma mixtures, as well as platelet concentrates, have been disclosed for tissue adhering procedures, and may rapidly form coagulums in delivery conduits during delivery procedures. Synthetic polymers such as cyanoacrylate adhesives or the like may also be used for tissue adhering or sealing procedures and which may cure in the delivery conduit such that suction withdrawal may be beneficial.

Still further, other fluids in addition to or in the alternative to tissue adhesives or sealants may have curing properties during delivery which would benefit by the clearing mode of operating the present inventive delivery device. For example, drug delivery fluids such as synthetic polymer substrates PEG, bioerodable polymers, non-erodable polymeric excipients, hydrogels, cultured cells, or various other forms of pharmaceuticals such as growth factor or biologics may be delivered as a substrate which clogs a dispensing conduit during medical fluid delivery procedures.

In addition to the broad field of substrates which may be suitable for use with the present invention, the present invention is also not limited to only the particular structural embodiments which are described in detail above. For example, Figures 18A-C show a further variation of both the supply device portion and the applicator portion of the medical fluid applicator invention. Furthermore, Figures 19-20C show another alternative variation for the applicator portion of the medical fluid applicator.

The medical fluid applicator 500 shown in overview in Figures 18A-C includes all of the internal componentry shown and described for the medical fluid applicator variations above, with some modifications to the dispensing and suction actuating assemblies in the supply device portion, and also to the applicator tip configuration of the applicator portion.

Figures 18A-B show applicator portion 503 of medical fluid applicator 500 to include an alternative variation for applicator tip 510 to that shown for the previous embodiments. Due to the elongated dimensions for applicator tip 510, it is believed that this variation has particularly beneficial application in moderately invasive surgical procedures for tissue adhesion or wound sealing, such as in less-invasive bypass procedures that are previously known and described in the art. It is to be appreciated by reference to Figures 18A-B in view of the previously shown and described embodiments that the internal structures of applicator portion 503 not shown are similar to that described for applicator portion 3 of those previous embodiments.

For example, applicator portion 503 includes a dispensing conduit that has a branched portion and a mixing portion, a suction conduit, a clearing conduit, and a shuttle valve such as those components previously described. However, in this variation, the branched portion of the dispensing conduit, the suction conduit, and the clearing conduit are all provided in an elongated form through the extended length of applicator tip 510. The mixing conduit component of the dispensing conduit, and also the distal portion of the shuttle valve which includes the dispensing and clearing valve portions, are preferably located in the distal region 512 of applicator tip 510. It is to be further understood that the suction conduit and the mixing portion of the dispensing conduit terminate distally in tip suction aperture 512 and tip dispensing aperture 524, respectively, as shown in Figure 18A.

The actuating assembly for medical fluid applicator 500 is further shown in Figure 18A, and includes a handle 505 which has an actuating trigger 520 coupled therewith. This variation is adapted for single handed use in actuating fluid dispensing. By gripping handle 505 and actuating trigger 520 in a user's hand, compressing the trigger against the handle actuates the dispensing assembly within the device to dispense fluids a predetermined incremental amount. Actuating trigger 520 includes a spring-bias and a

full "stroke" range of motion which may be similar to the spring-bias and "stroke" described for the previous embodiments, such as with reference to Figure 5. Furthermore, the coupling of actuating trigger 520 to the other components of the actuating assembly not shown may be similar to that described for the previous variation of Figure 5, including the rack and pawl mechanism, and further including the audible and visual volume indicators previously described, as would be apparent to one of ordinary skill.

Also shown in Figure 18A is a valve actuator 530 which is also coupled to handle 505 and is also adapted for single-handed use in a similar manner as actuating trigger 520. By depressing valve actuator 520 to various actuated positions relative to handle 505, a valve manifold not shown within the interior of the supply device portion 502 is adjusted to various positions to create a venting pathway, a suction pathway, or a clearing pathway. Furthermore, actuated motion of valve actuator 520 also selectively positions the shuttle valve component of the device not shown in order to close suction to the suction conduit and open communication for suction to the mixing portion of the dispensing conduit via the clearing conduit. The mechanisms provided by the valve manifold and the shuttle valve in this variation are the same as those shown and described for the previous embodiments, but for the coupling of valve actuator 520 to the manifold and the shuttle valve, which would be apparent to one of ordinary skill by this disclosure.

A further variation of the medical fluid applicator of the present invention is provided by reference to medical fluid applicator 600 in Figures 19A-20C. This variation includes all of the mechanical dispensing features, valving features, and actuating features of the previous embodiments, but includes only a single dispensing conduit 660 at the applicator tip 610 and omits the suction conduit feature of the previous embodiments. By this alternative variation, it is to be understood that the utility of applied suction for tissue preparation may be done in series with fluid dispensing through the same conduit, and need not be contemporaneous to fluid delivery through two, adjacent conduits as provided in the previous embodiments.

In this single conduit variation of the invention, it is contemplated that the device may be used during one particularly prolonged period for suction and in another prolonged period for dispensing. For this reason, it is less convenient to have a constant spring-bias to a rearward position for the shuttle valve, such that the valve must be manually actuated against the resting spring bias in order to close the dispensing pathway and open the suction/clearing pathway through the common conduit. Therefore, it is preferred in this variation to provide a detent locking mechanism not shown so that the shuttle valve may be temporarily locked into one of two positions for dispensing or clearing, respectively, such as the detent locking mechanism which is commonly used in opening and closing ball-point ink pens.

Figures 20A-C show various operating modes of this variation in a similar manner to Figures 12A-C in describing operation of the previous embodiment associated therewith. In Figure 20A, valve manifold 630 is shown in a resting or venting position similar to that of Figure 12A. In Figure 20B, valve manifold 630 is shown actuated in a first suction position. In Figure 20C, valve manifold 630 further shown in a second clearing position, wherein the distal mixing region of dispensing conduit 660 is retrogradedly cleared of its contents.

It should be understood by one of ordinary skill from the preceding disclosure that the present invention is broader than the particular embodiments described. Suitable equivalents, alternatives or modifications to the particular described embodiments which are apparent to one of ordinary skill from this disclosure are considered to be included within the scope of the present invention.

CLAIMS:

1. A suction applicator intended to be manually held and operated and comprising:

a) a suction applicator tip to apply suction to a work surface;

b) a suction connector connectable with a suction source;

c) a suction pathway extending between the suction connector and the applicator tip in an operative configuration of the applicator;

d) vent pathway connectable to vent the suction pathway to atmosphere; and

e) a manually operable suction control member to control suction at the applicator tip; wherein the suction control member is selectively movable between a first position providing full venting of suction to atmosphere with no suction applied to the applicator tip and a second position with no venting to atmosphere and full suction applied to the applicator tip;

f) a dispensing aperture formed in said applicator tip;

g) a dispensing pathway formed by and extending through said applicator tip from said dispensing aperture characterized in that the suction control member has an intermediate position wherein the suction pathway is partially constricted to apply partial suction to the applicator tip and partially vented to atmosphere.

2. A suction applicator according to claim 1 characterized by the suction control member being movable to a third position wherein the suction pathway is connected with the dispensing pathway to clear the dispensing pathway.

3. A suction applicator according to claim 1 characterized in that the suction pathway comprises a variable suction throat operable to vary the suction applied to the applicator tip.

4. A suction applicator according to claim 1 characterized by the suction control member comprising a movable valve member having ports to effect the variation of the suction and venting as the suction control member is moved.

5. A suction applicator according to claim 1 characterized by comprising a switching valve to switch the communication of the suction pathway between the suction applicator tip and the dispensing pathway, and in that the switching valve is actuated by movement of the suction control member into the clearing position.

6. A suction applicator according to claim 1 characterized in that the fluid to be dispenses comprises a tissue sealant, and said dispensing passageway is disposed adjacent the suction pathway for cooperative application of suction and the tissue sealant to a work surface.

7. A medical suction device according to claim 2 wherein said suction control member includes a vacuum manifold comprising i) a valve housing having a suction port in fluid communication with the suction passageway and having a vent port providing the vent in communication with atmospheric pressure and having a clearing port in fluid communication with said dispensing pathway; and ii) a valve member movable within the valve housing between said first and second positions and forming a suction aperture and a vent aperture, the suction and vent apertures being constructed and disposed to translate across and register at least in part with the suction and vent ports, respectively, as the valve member moves between said first and second positions and also forming a a clearing aperture for registering at least in part with the clearing port as the valve member moves through said third.

8. A medical suction device according to claim 7 characterized in that the suction and clearing apertures are configured with a transverse dimension which varies in the direction of motion of the valve member, and are inversely oriented whereby, as the valve member moves, relative to respective stationary points, the transverse dimension of the suction aperture increases while that of the clearing aperture decreases and the transverse dimension of the suction aperture decreases while that of the clearing aperture increases.

9. A medical suction device according to claim 7, characterized in that the suction aperture in the valve member registers with the suction port in the valve housing to provide a variable suction throat of increasing cross-sectional area as the valve member moves from the first position to the second position.

10. A medical suction device according to claim 8 or 9, characterized in that the clearing aperture in the valve member registers with the clearing port in the valve housing to provide a variable clearing throat of decreasing cross-sectional area as the valve member moves from the first position to the second position.

11. A medical suction device according to claim 10, characterized in that one or both of the suction and clearing apertures has the shape of a diminished ellipse.

12. A medical suction device according to claim 8, characterized in that the suction and clearing apertures each have the shape of a diminished ellipse and are inversely oriented along the direction of motion of the valve member.

13. A medical suction device according to claim 12, characterized in that the suction and clearing apertures increase and decrease, respectively, in their cross-sectional areas, in a linear manner along the 0 direction of motion.

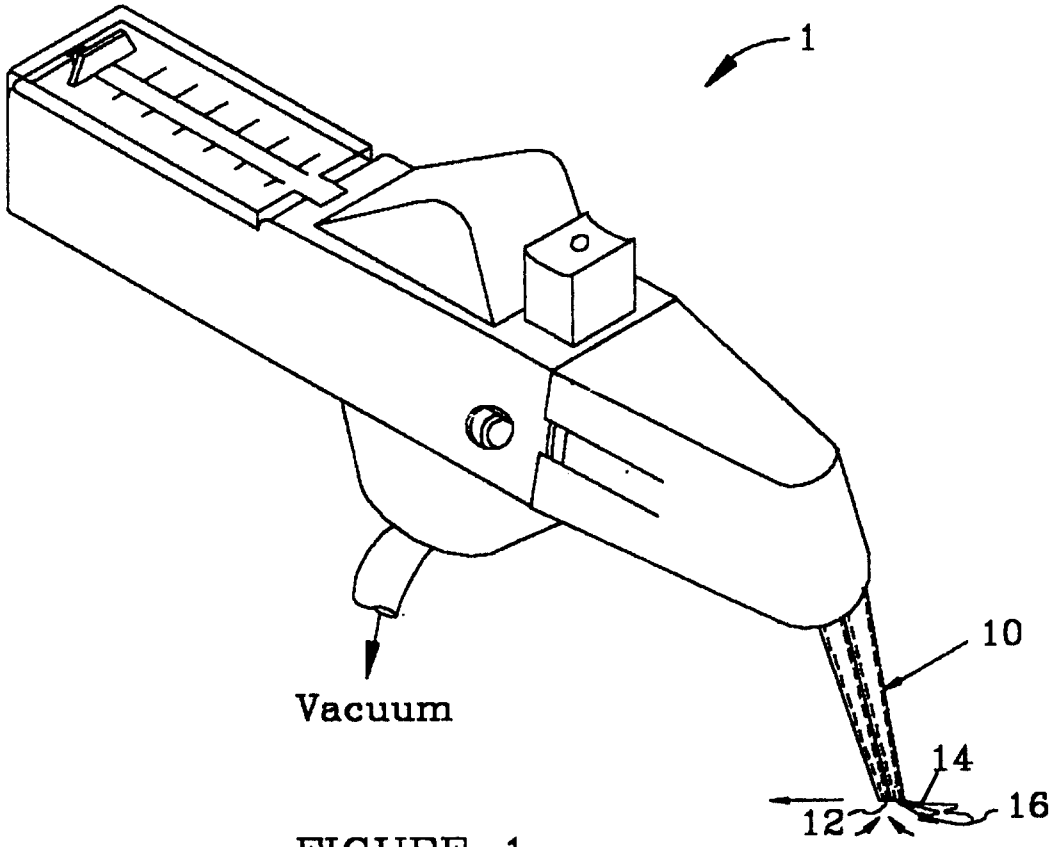

FIGURE 1

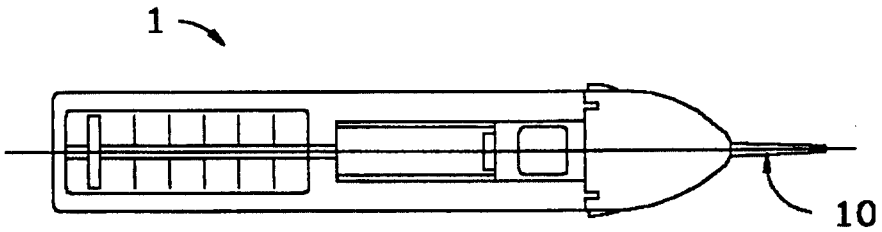

FIGURE 2A

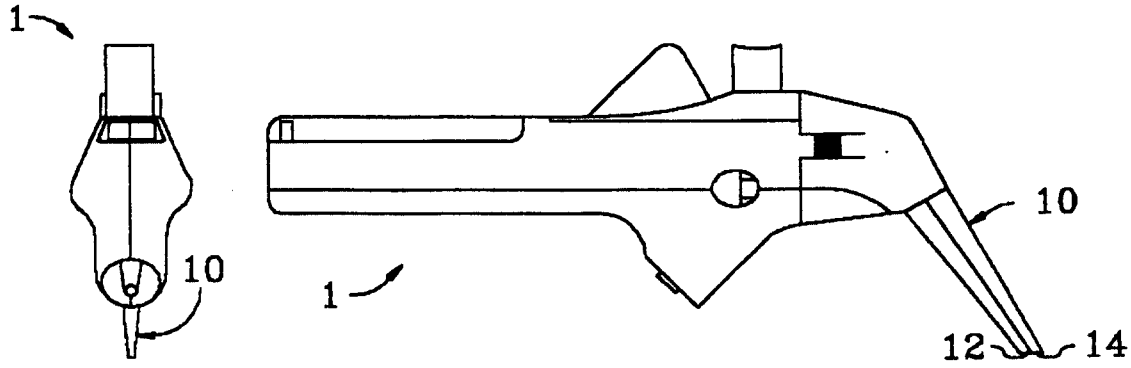

FIGURE 2C FIGURE 2B

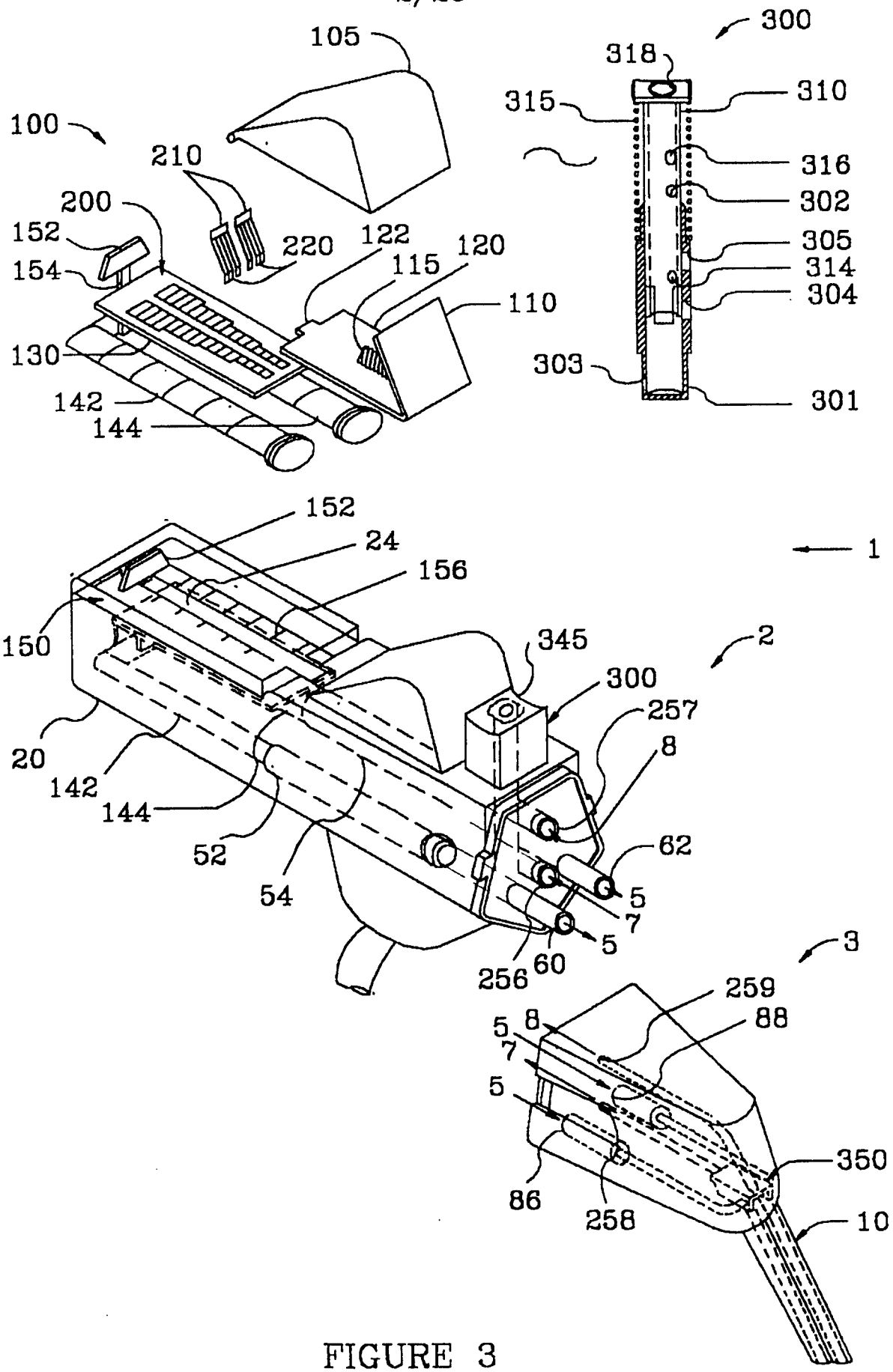
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FIGURE 3

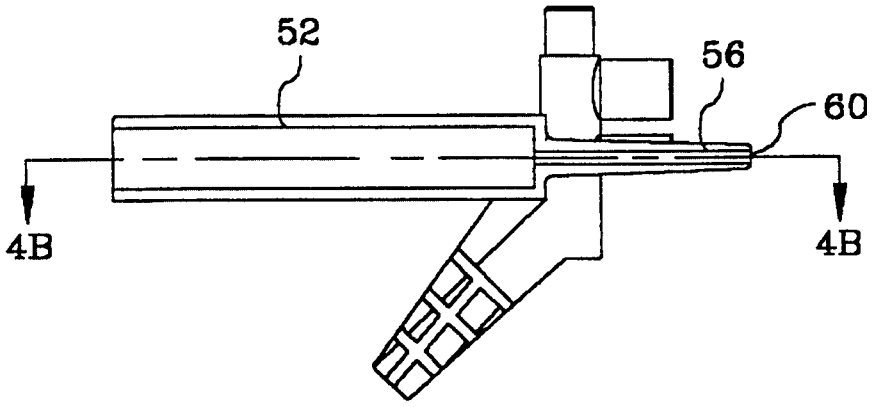

FIGURE 4A

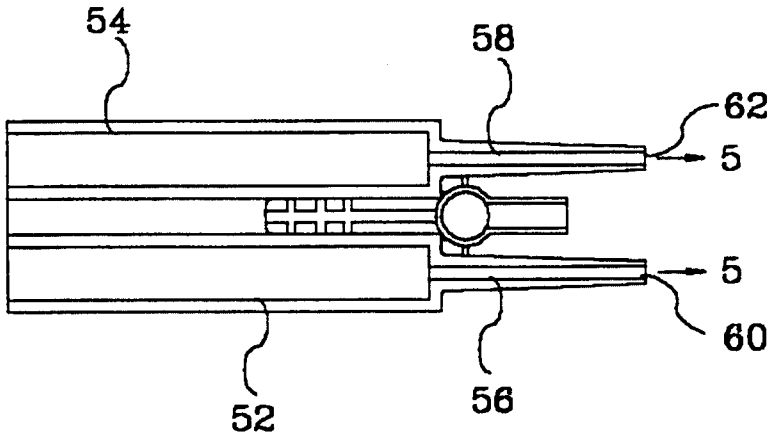

FIGURE 4B

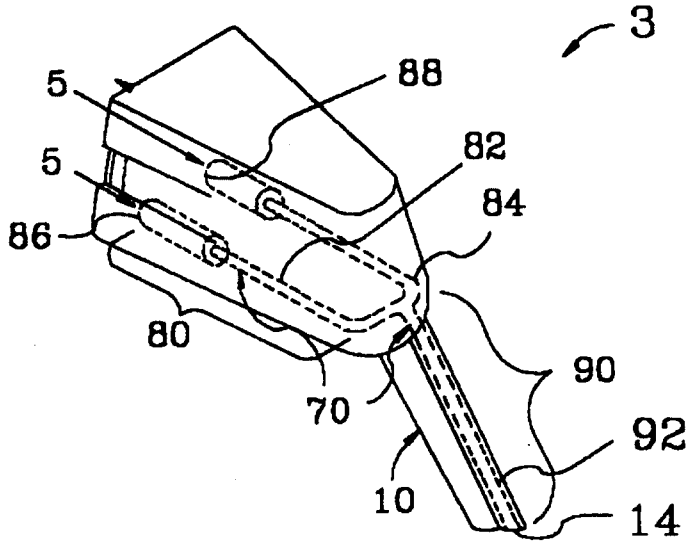

FIGURE 4C

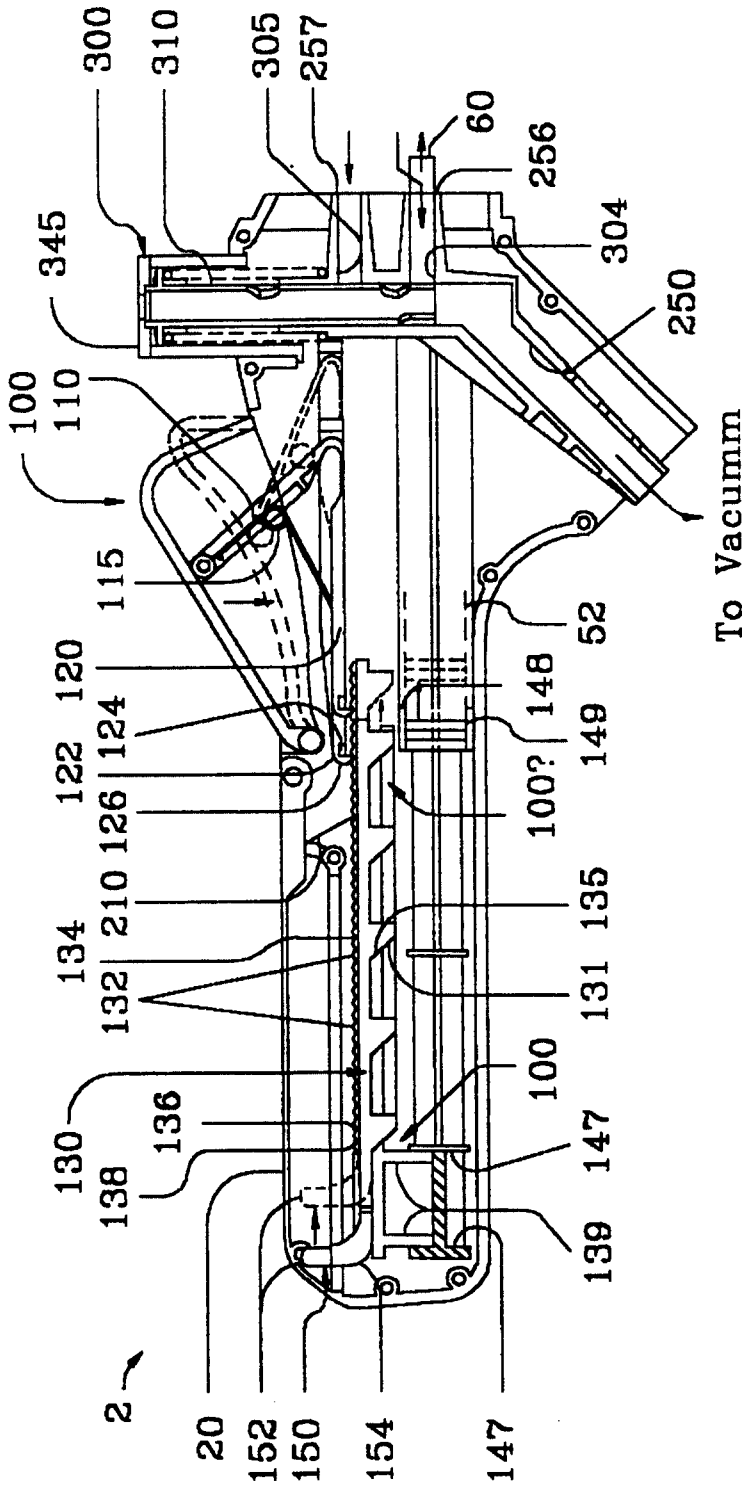

FIGURE 5

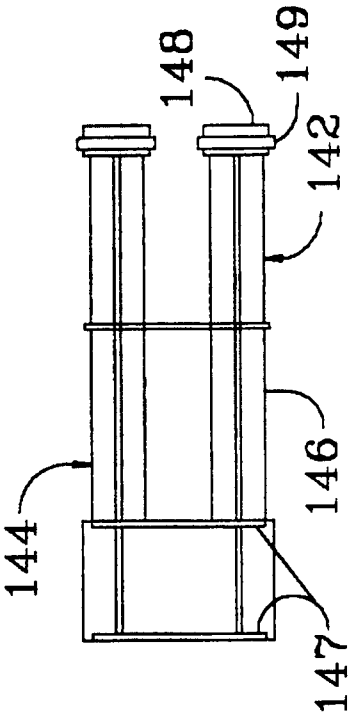

FIGURE 7

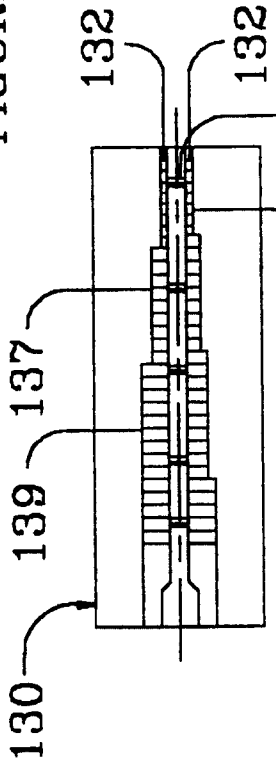

FIGURE 6

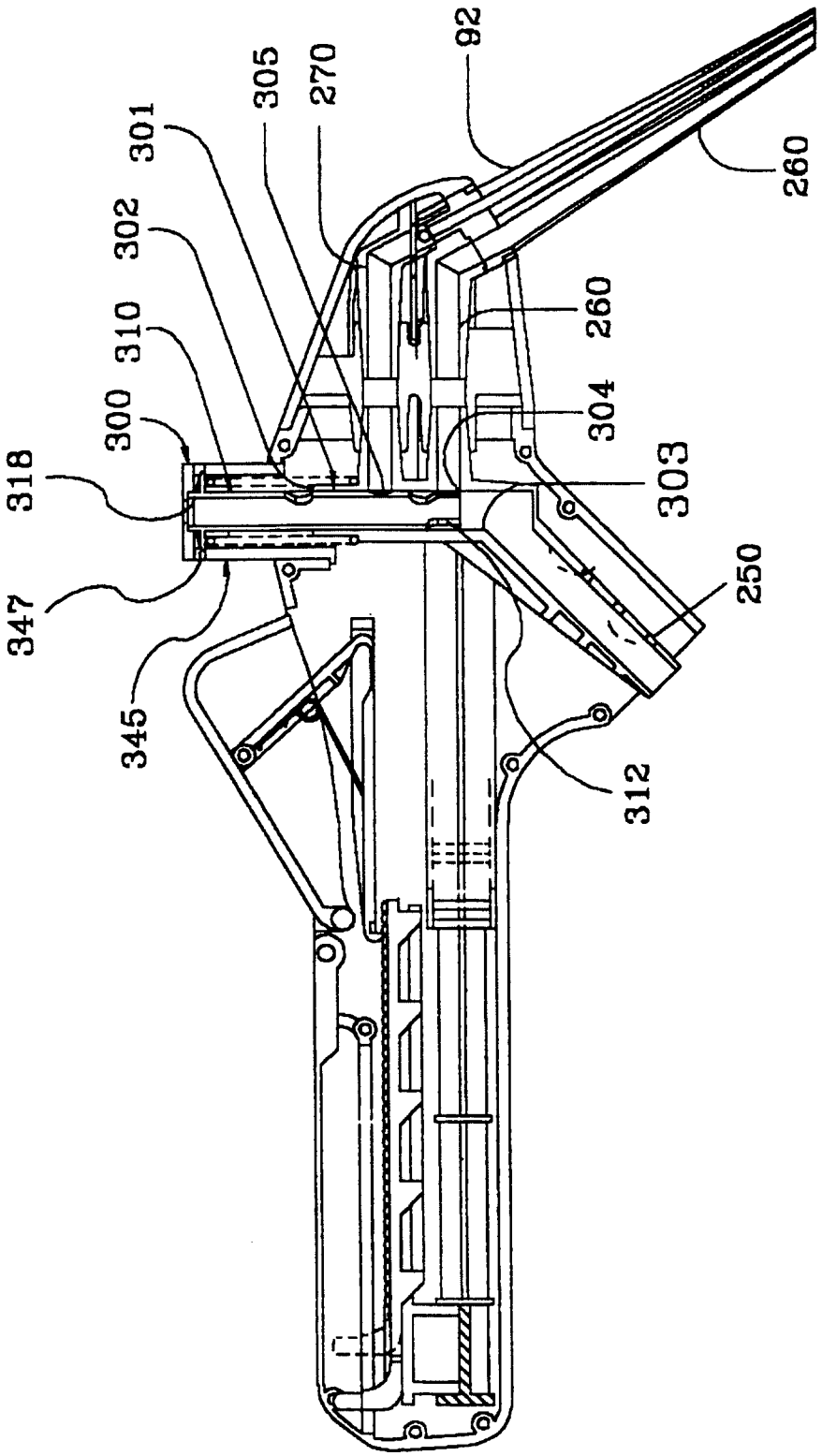

FIGURE 8

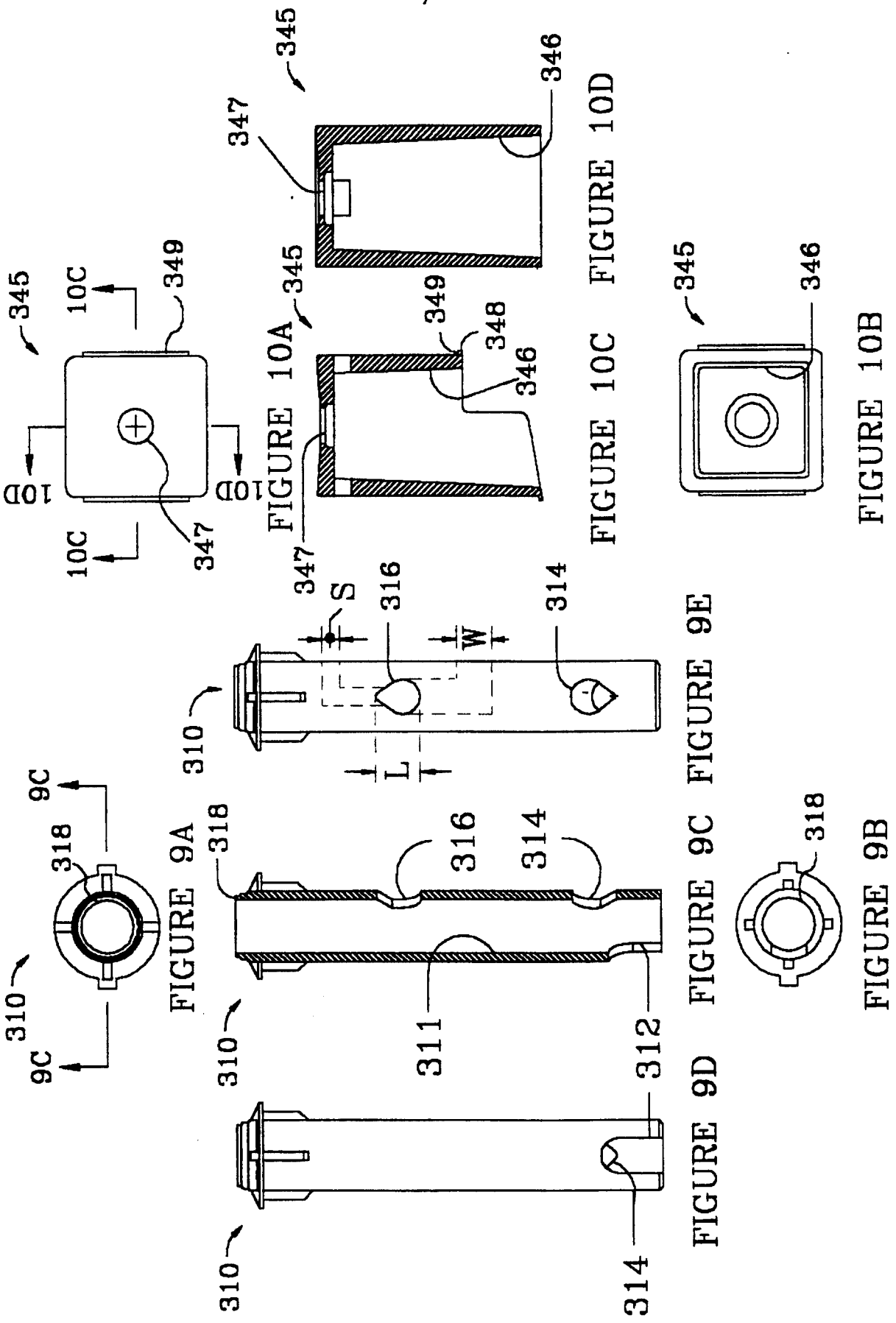
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FIGURE 10D
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FIGURE 10B
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FIGURE 10A
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FIGURE 10C
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FIGURE 9A
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FIGURE 9E
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FIGURE 9C
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FIGURE 9B
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FIGURE 9D

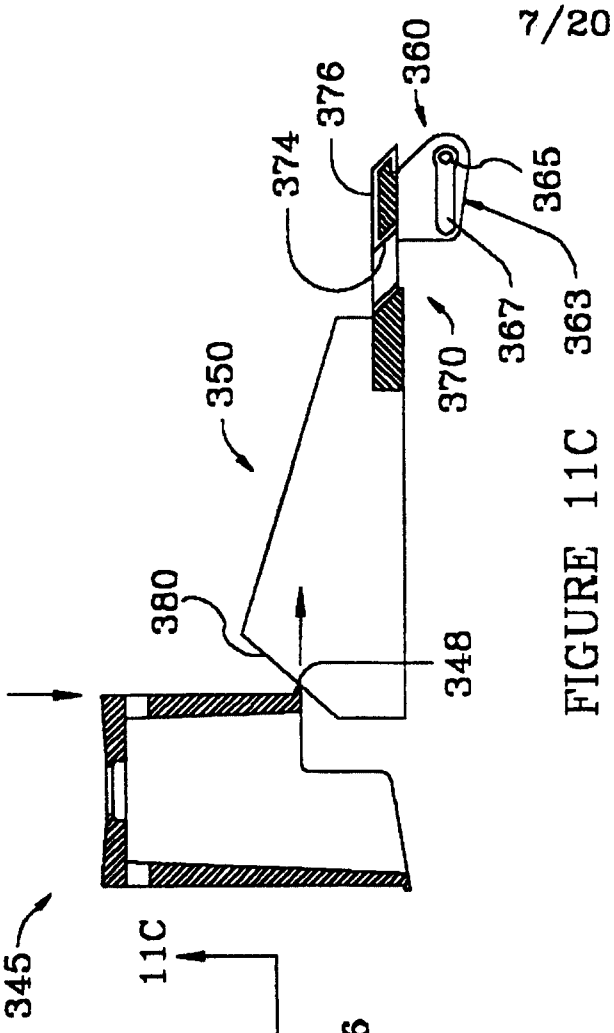


FIGURE 11C

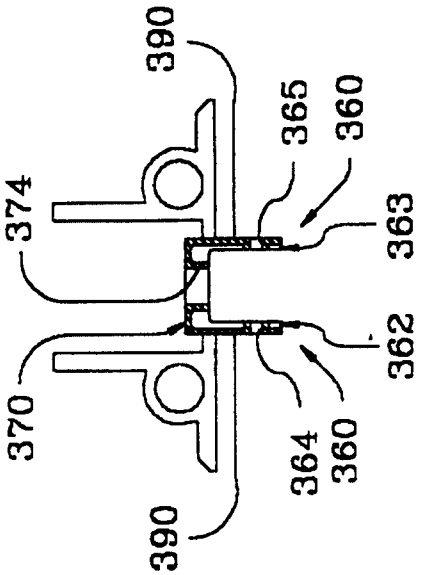


FIGURE 11D

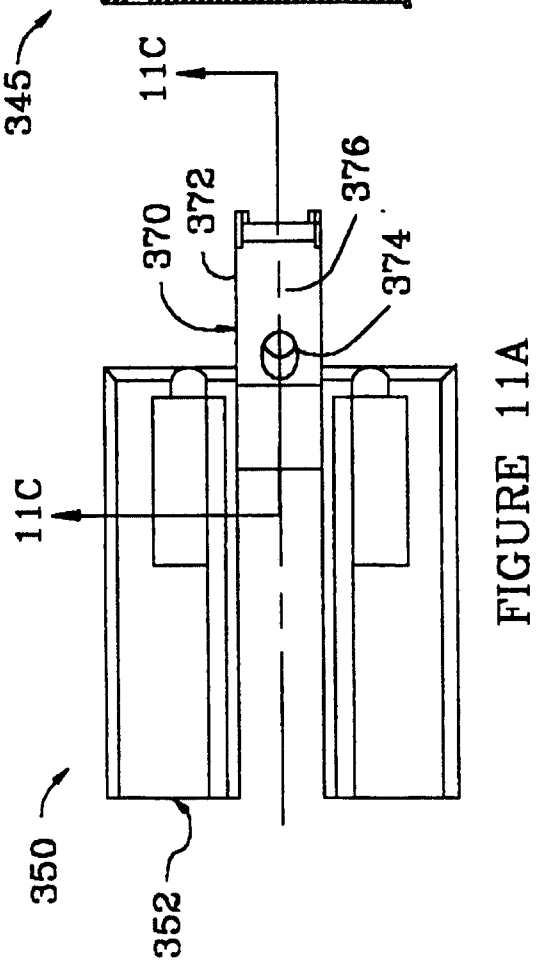


FIGURE 11A

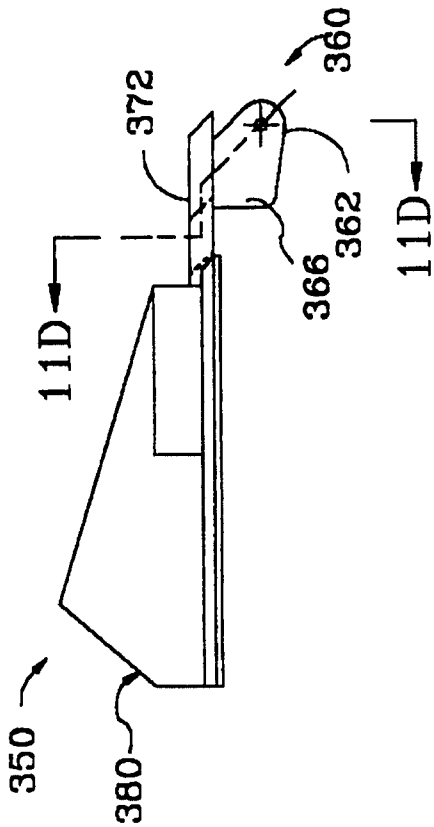


FIGURE 11B

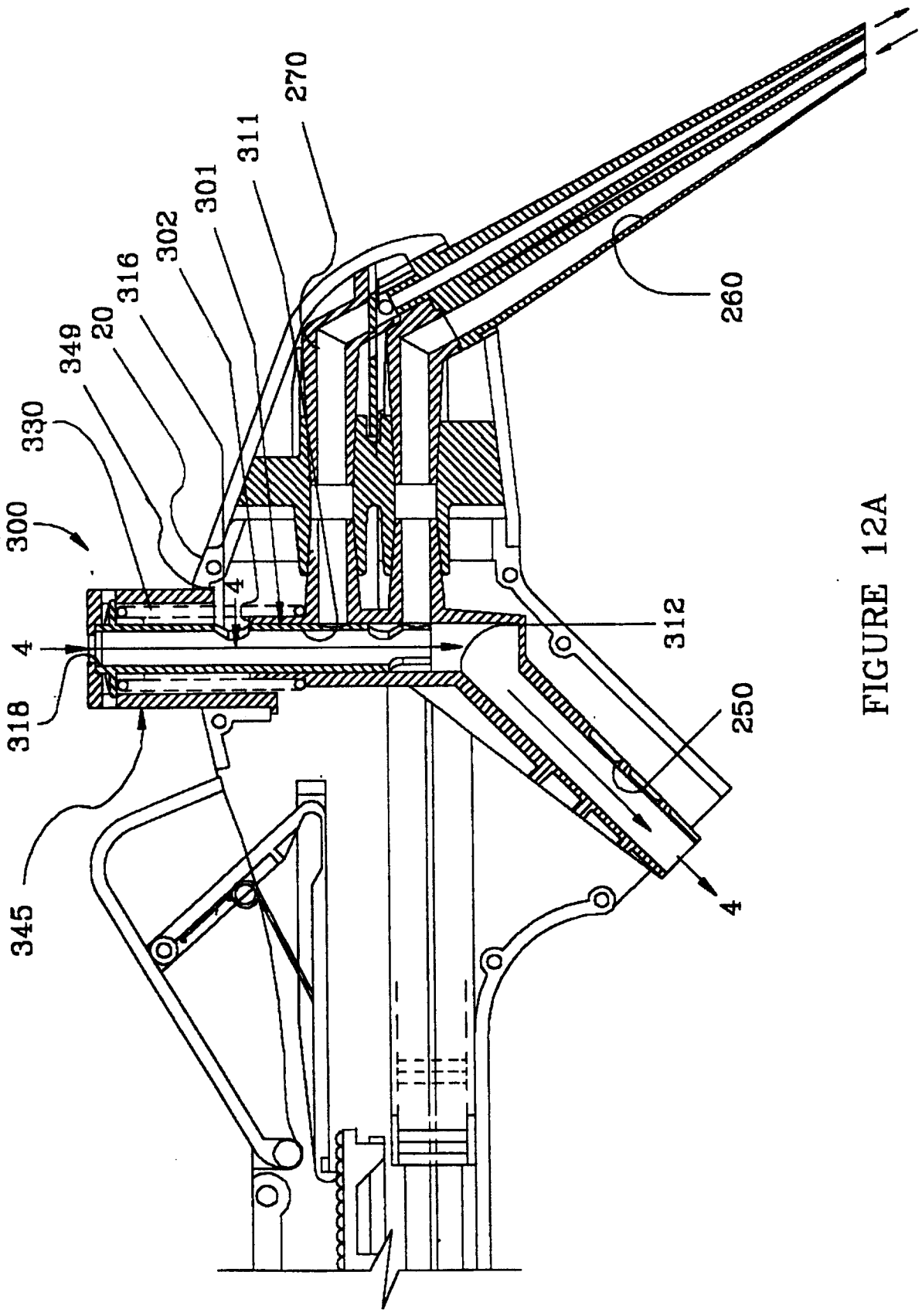


FIGURE 12A

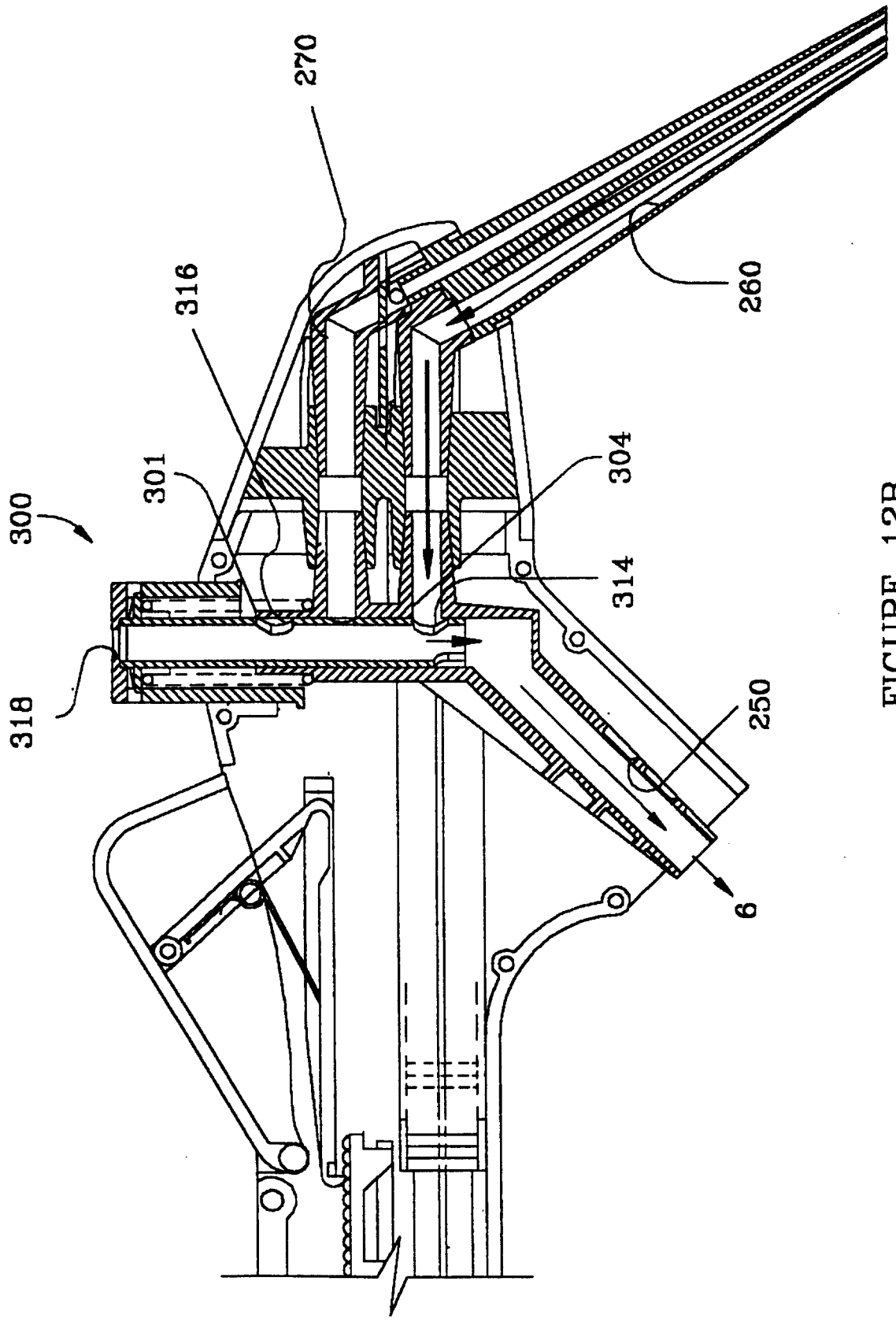


FIGURE 12B

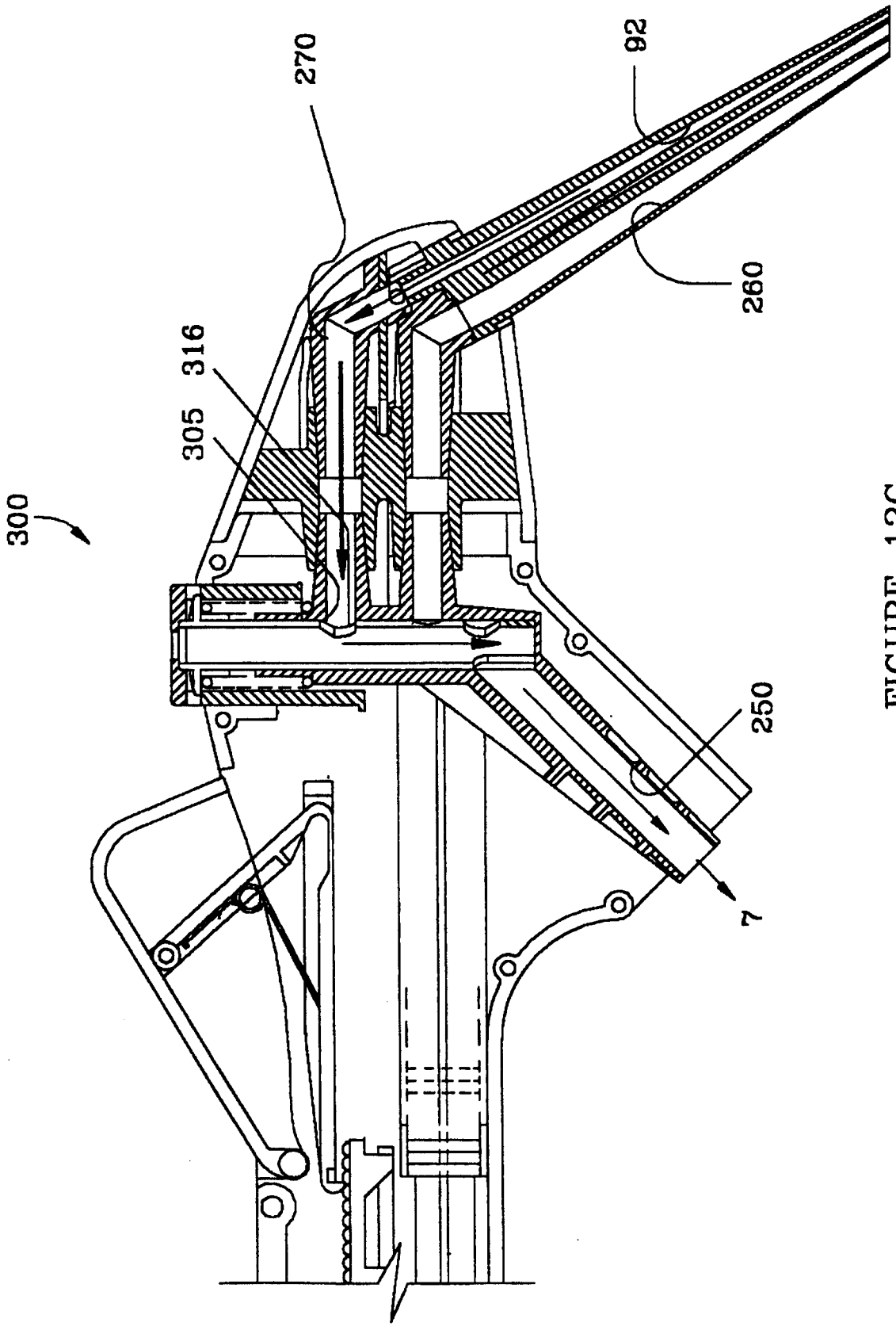


FIGURE 12C

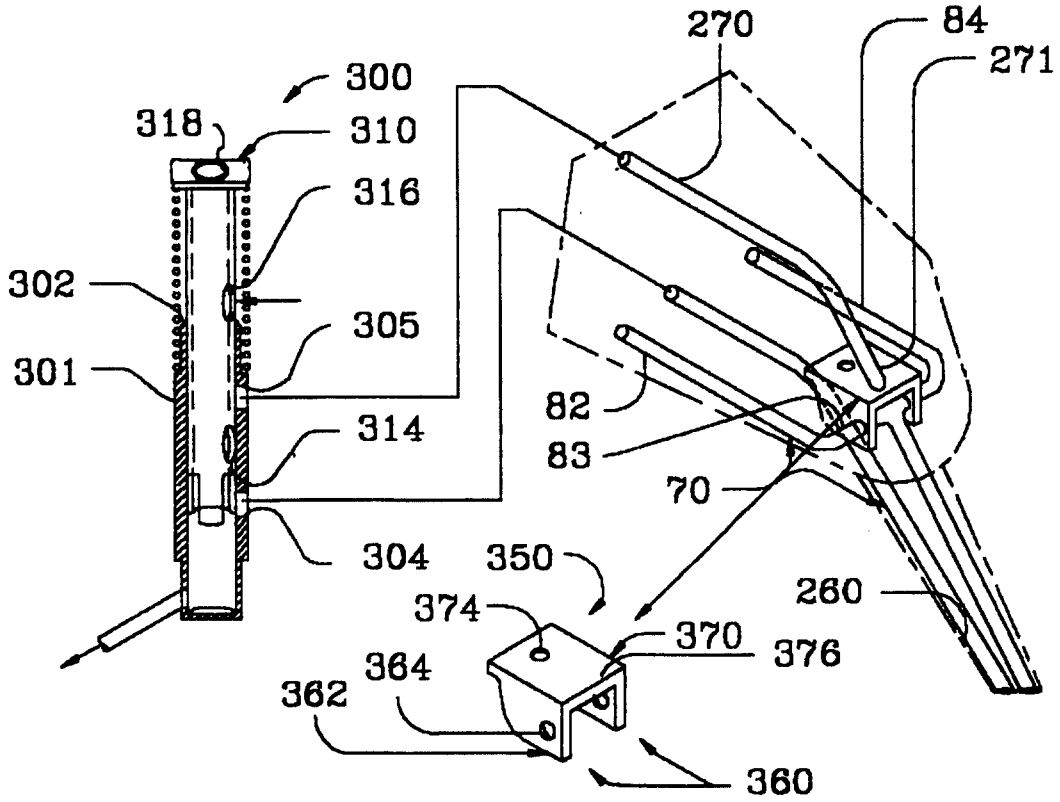


FIGURE 13A

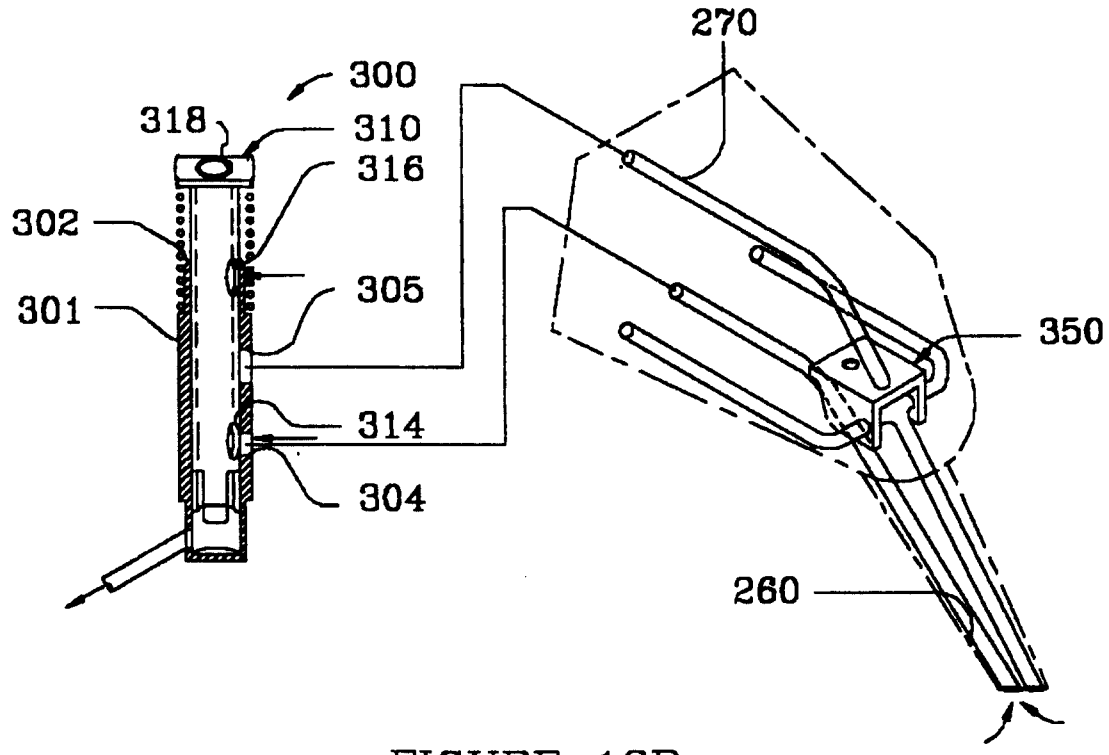


FIGURE 13B

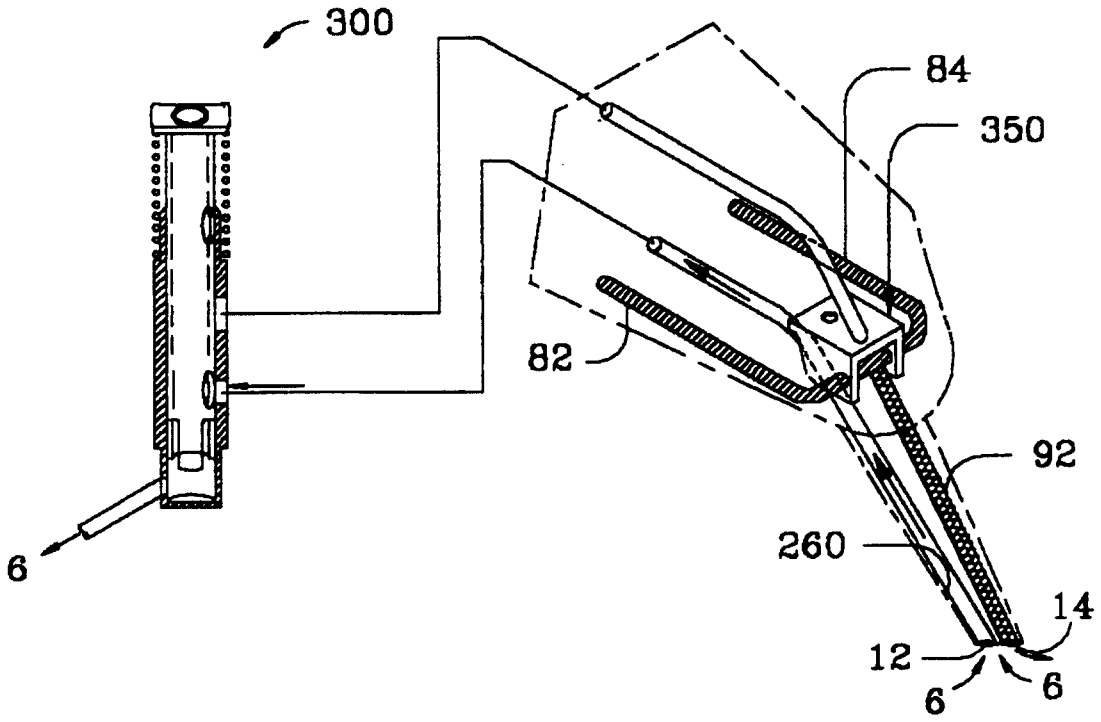


FIGURE 14A

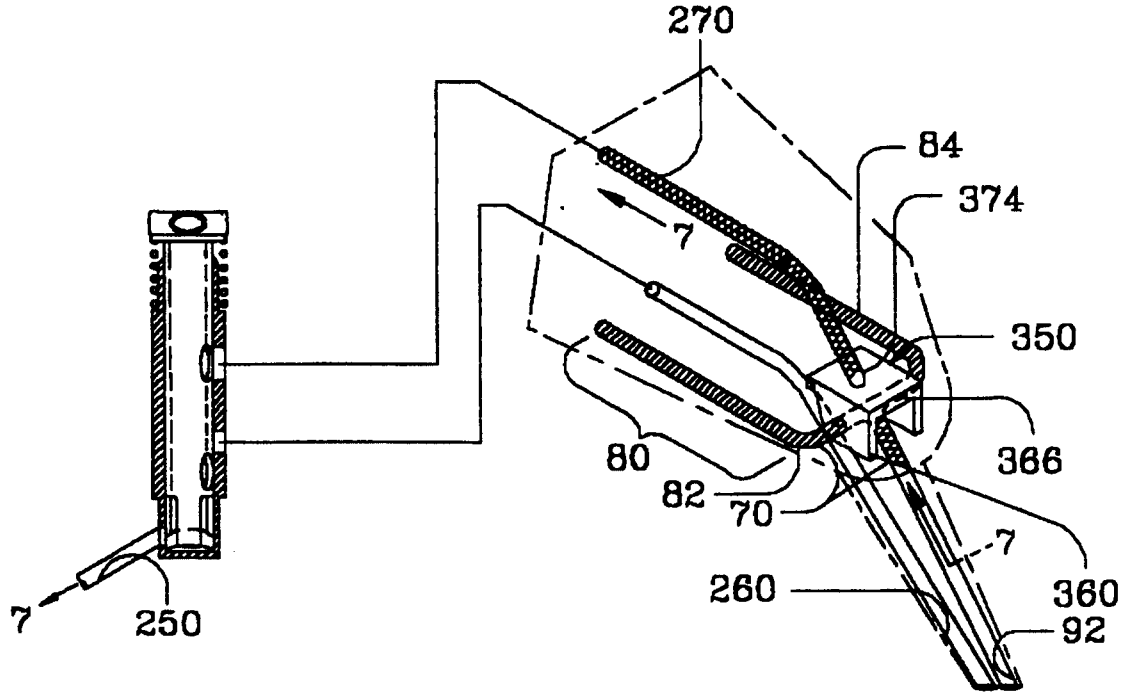


FIGURE 14B

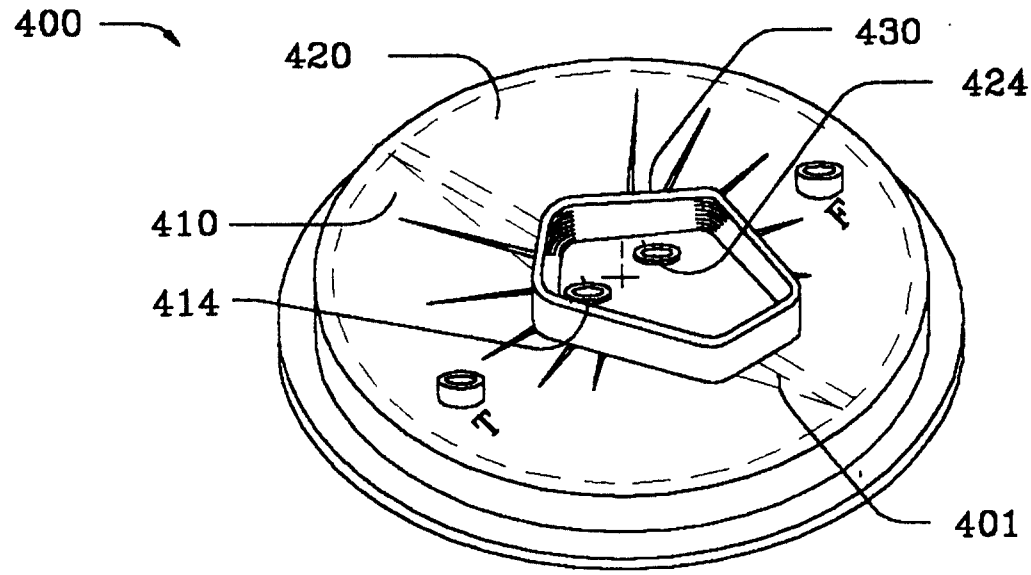


FIGURE 15

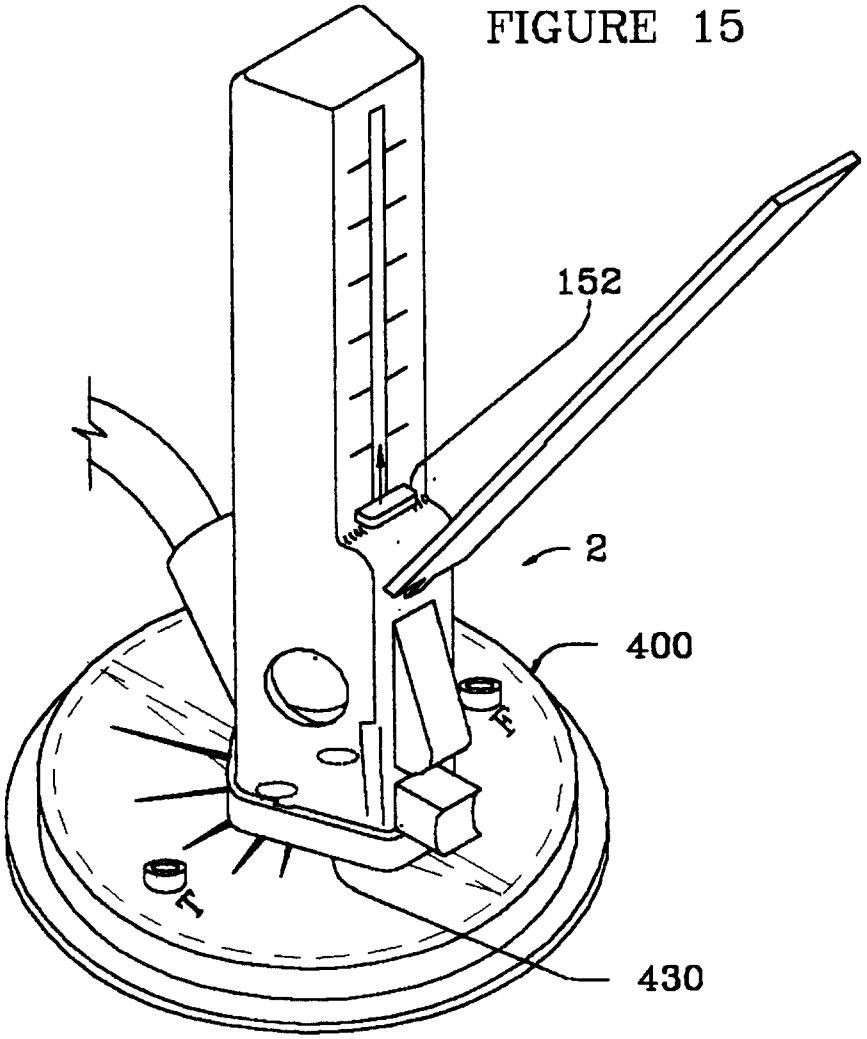


FIGURE 16

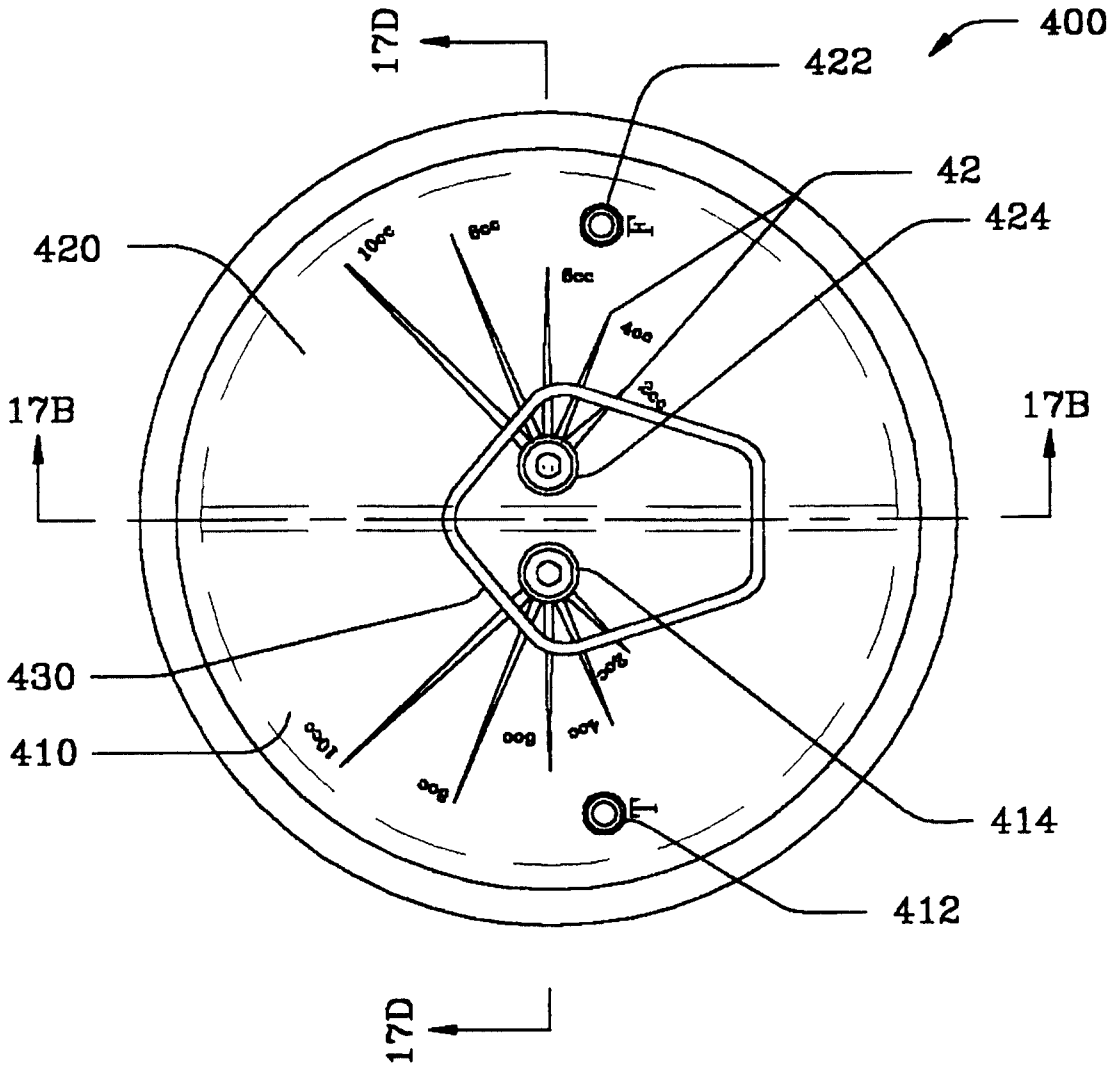


FIGURE 17A

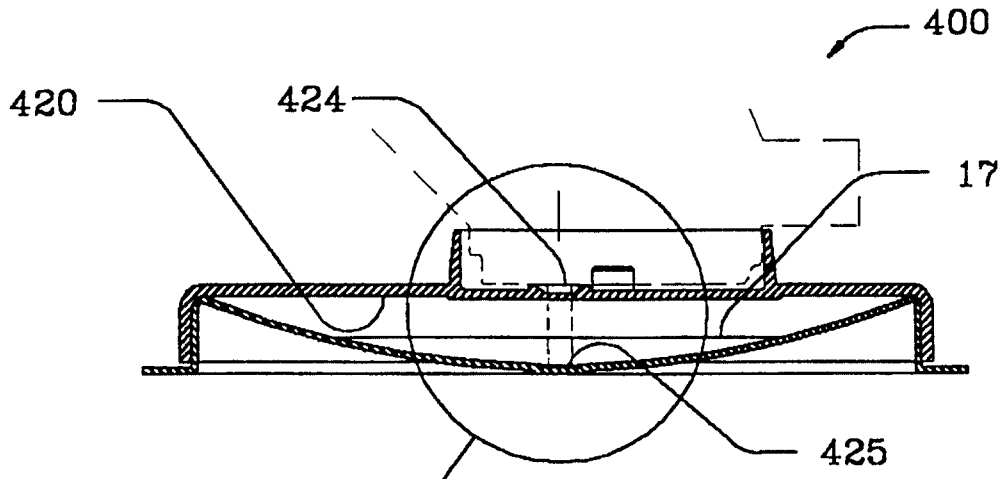


FIGURE 17B

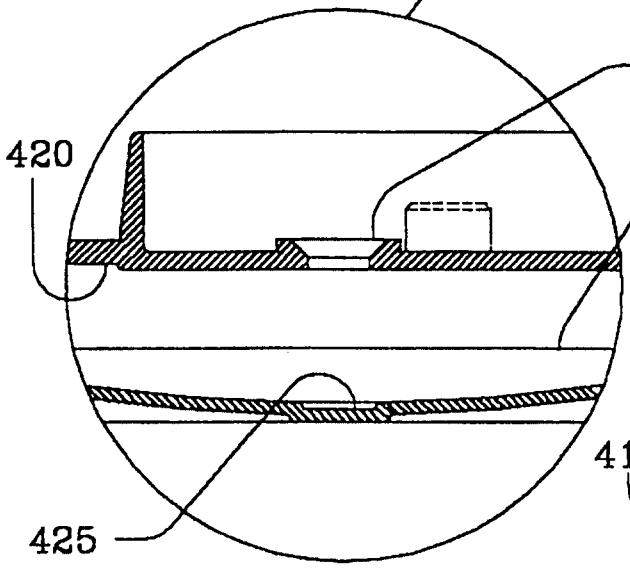


FIGURE 17C

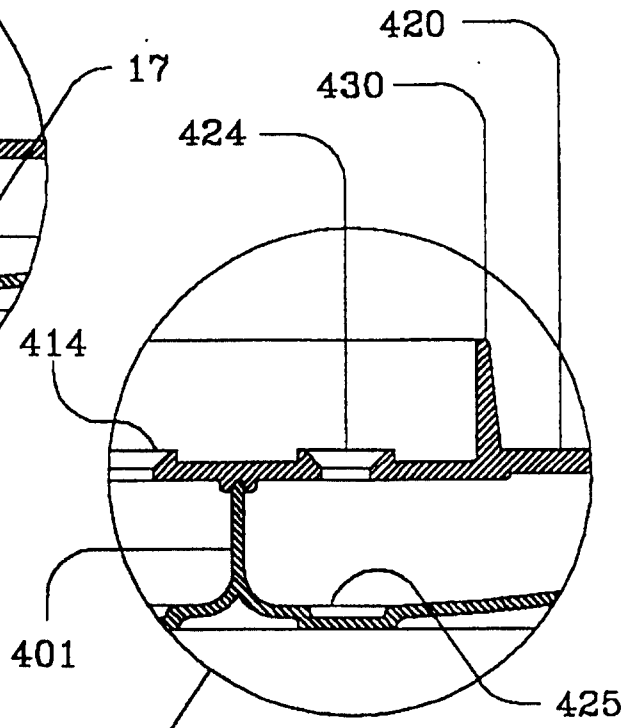


FIGURE 17E

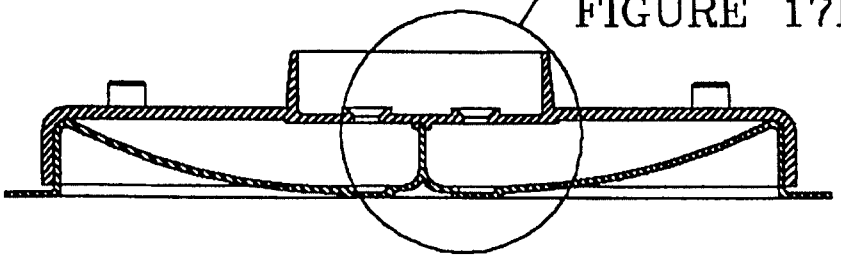


FIGURE 17D

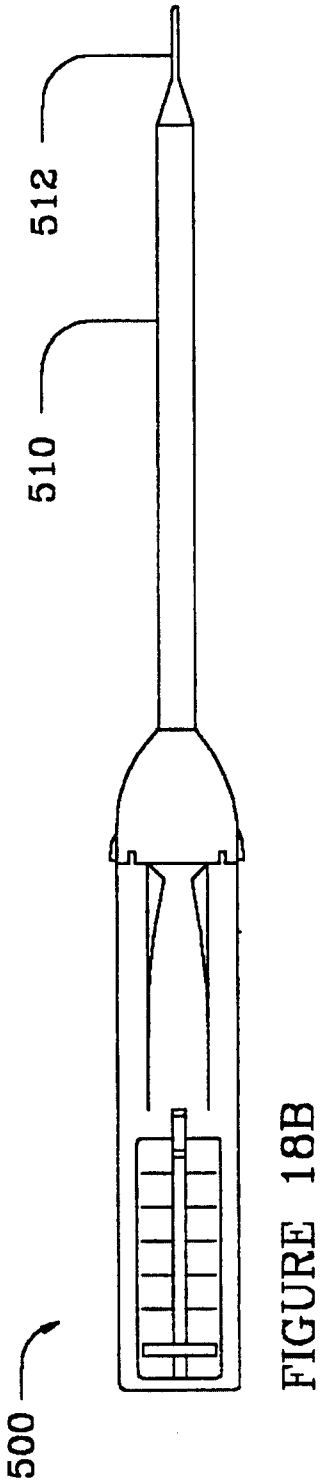


FIGURE 18B

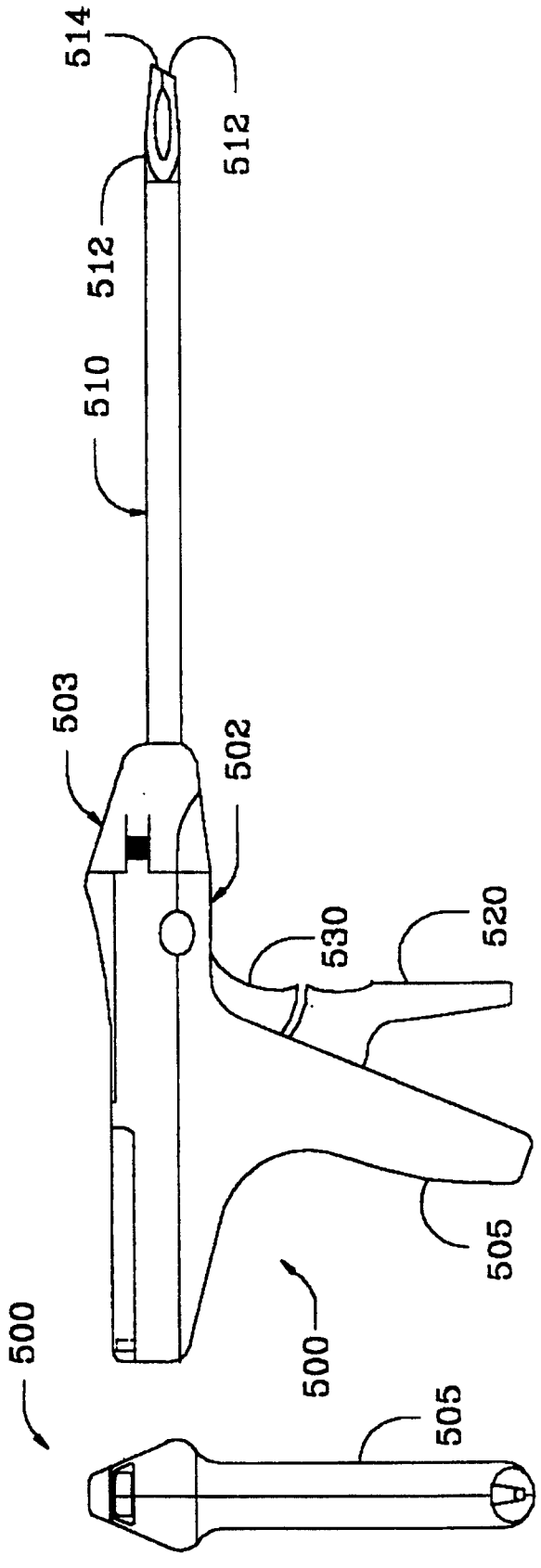


FIGURE 18A

FIGURE 18C

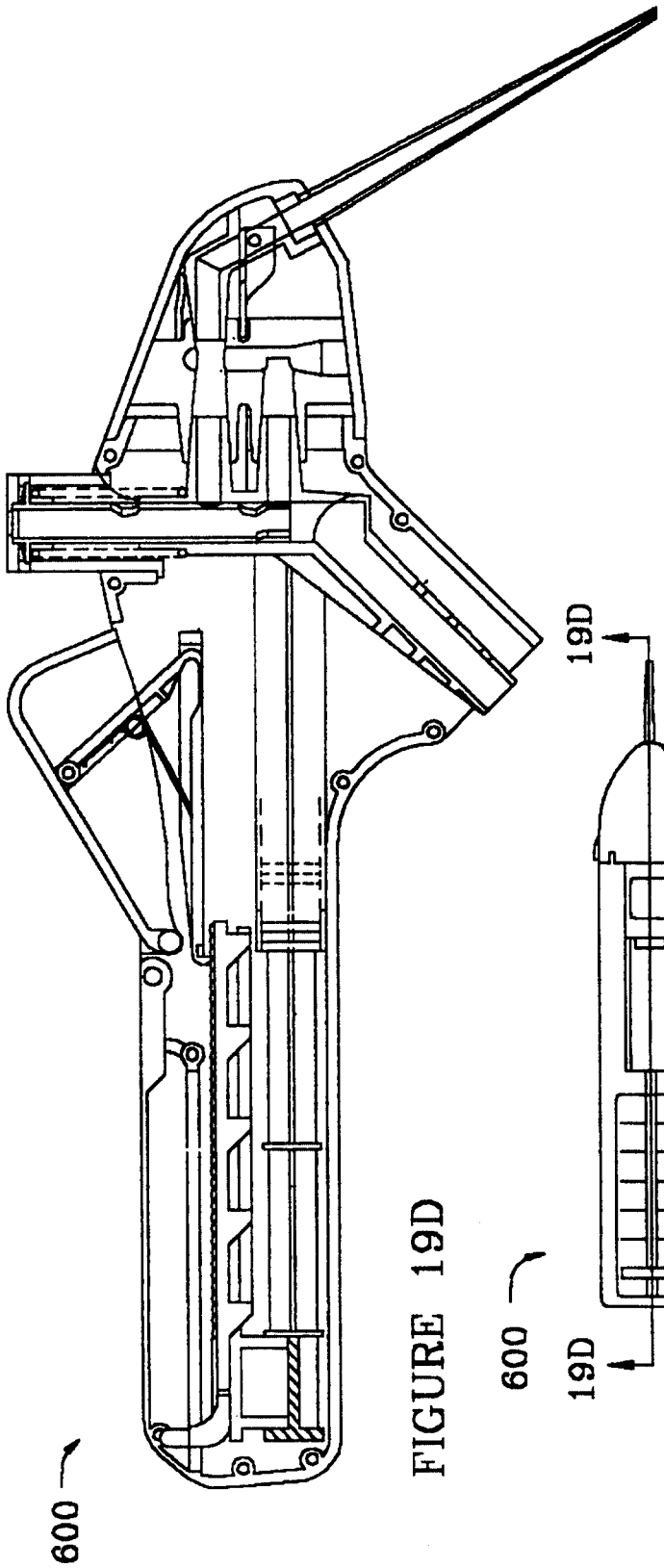


FIGURE 19D

FIGURE 19A

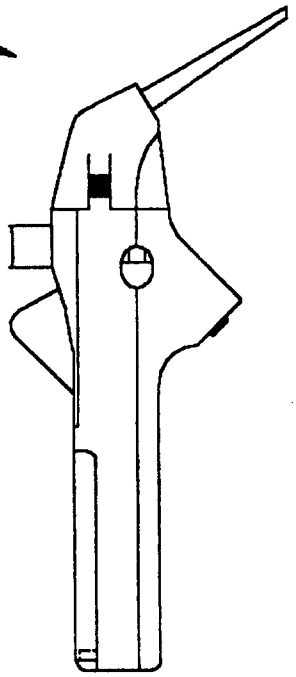


FIGURE 19B

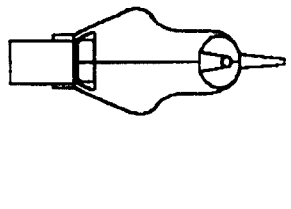


FIGURE 19C

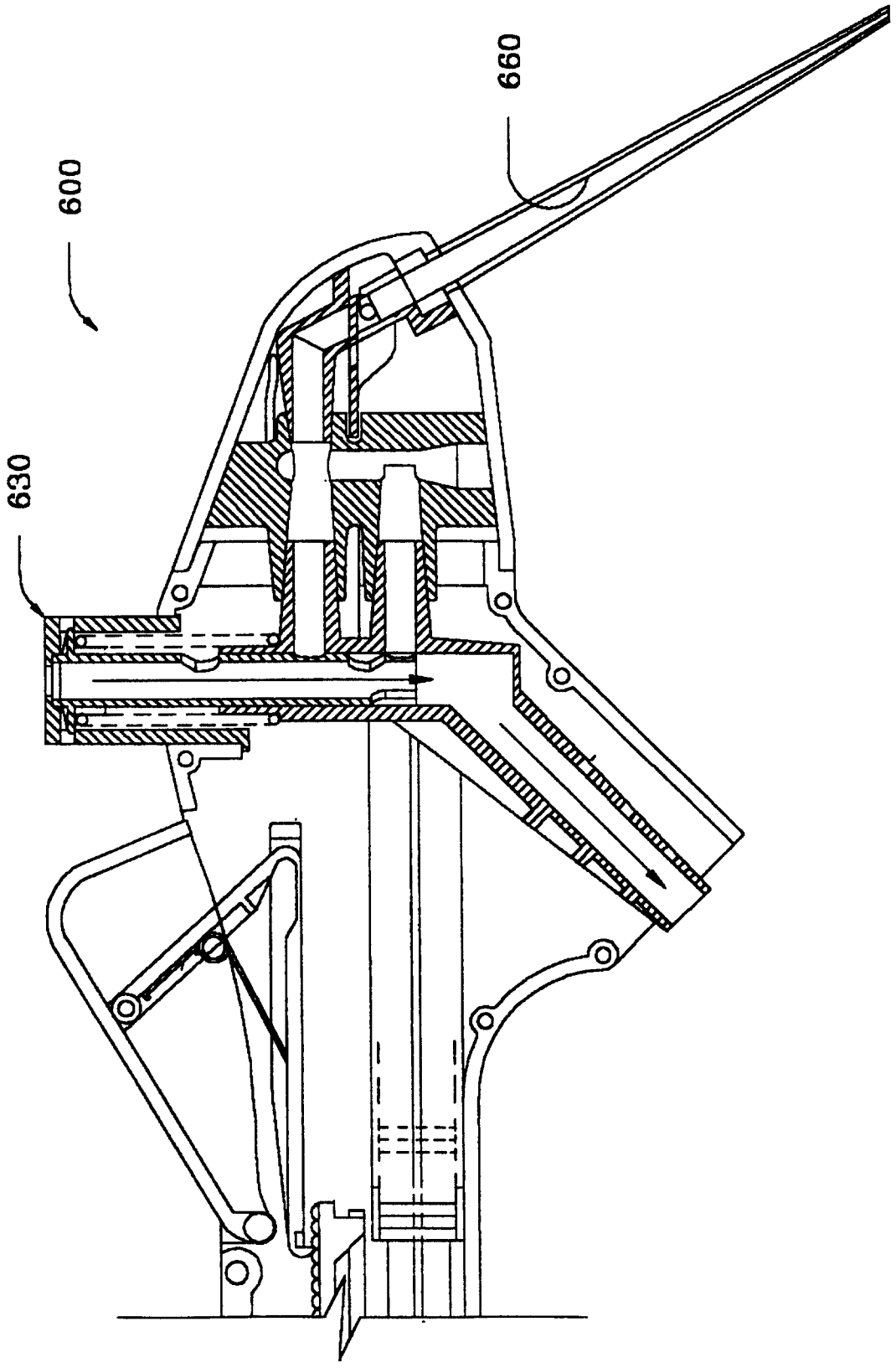


FIGURE 20A

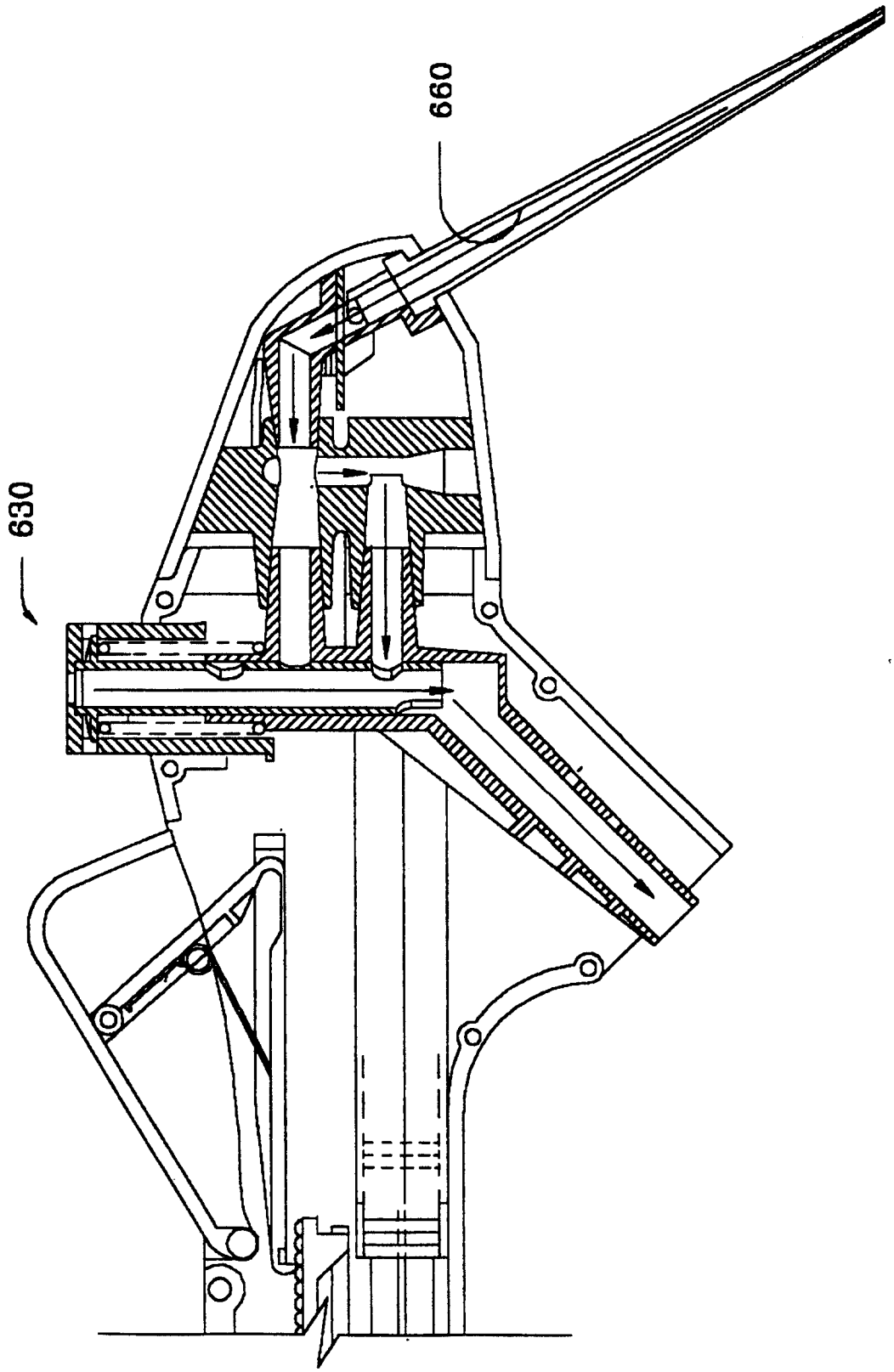


FIGURE 20B

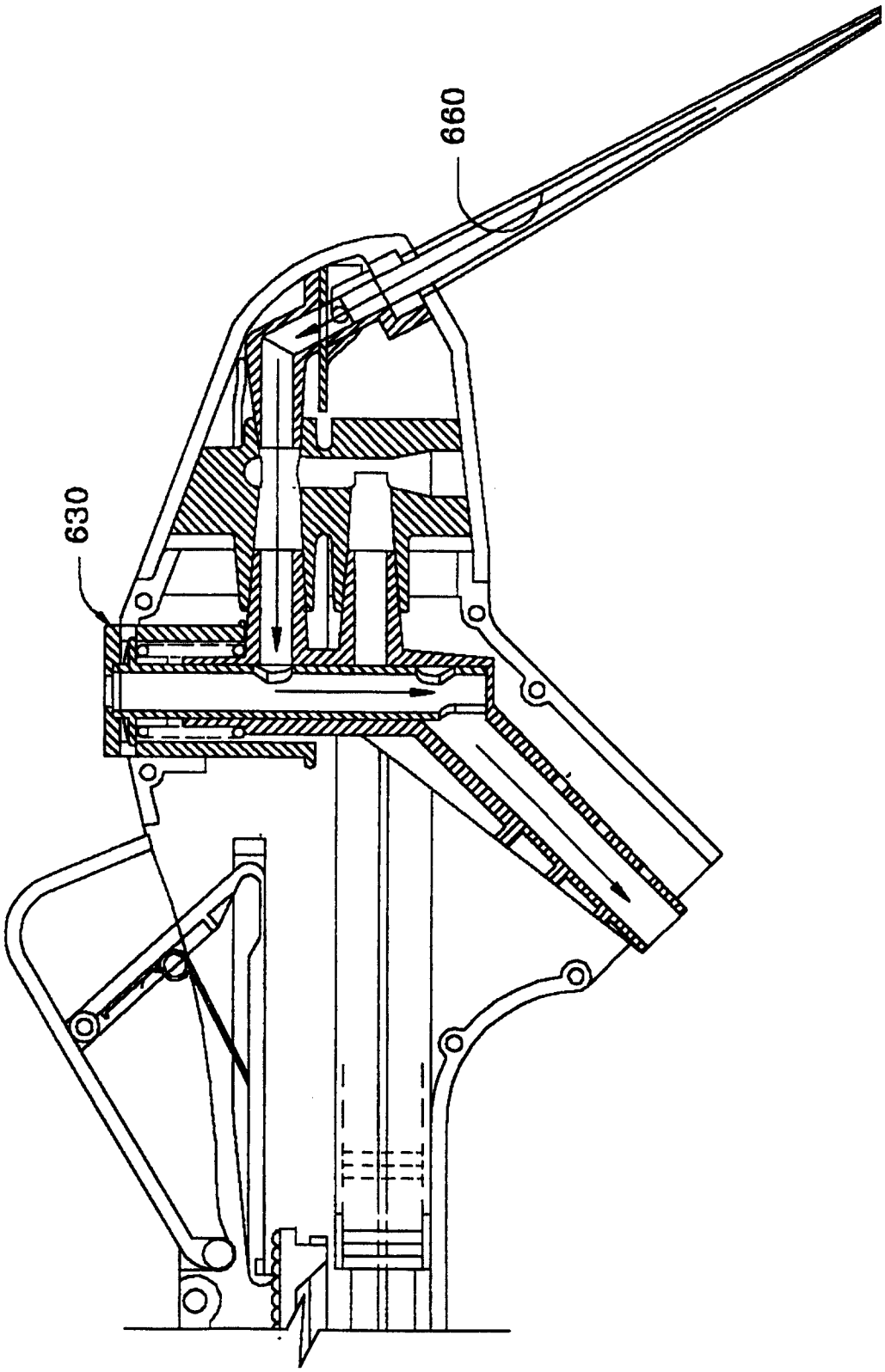
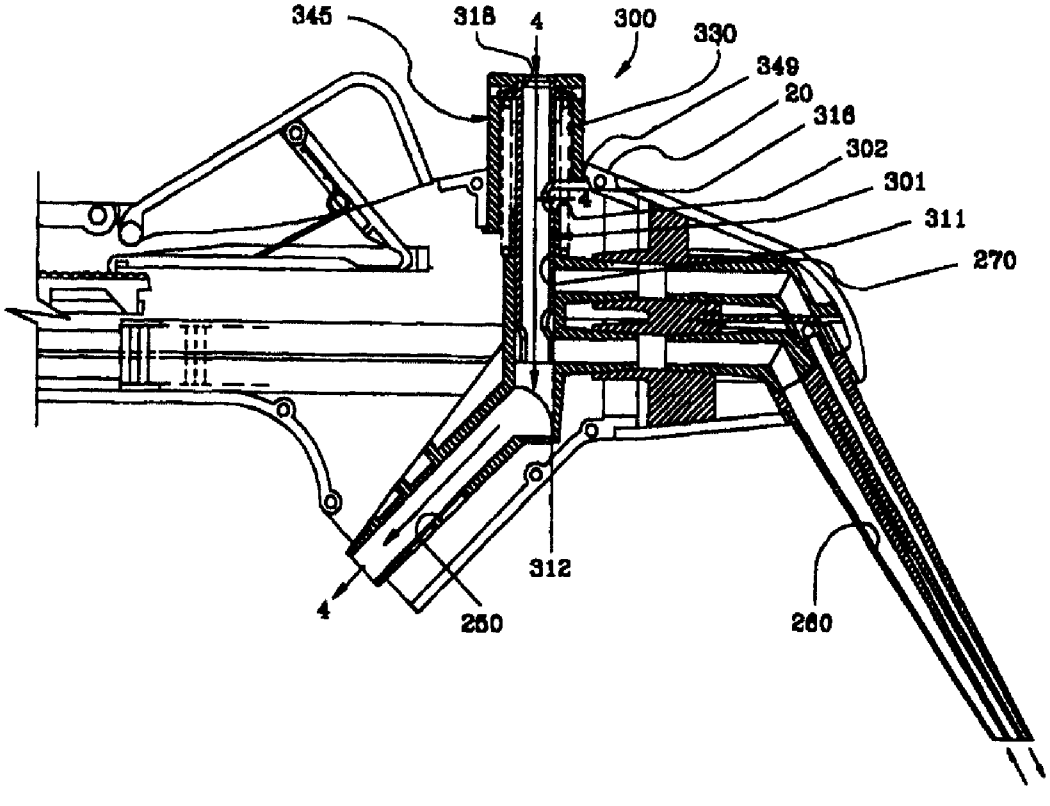


FIGURE 20C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