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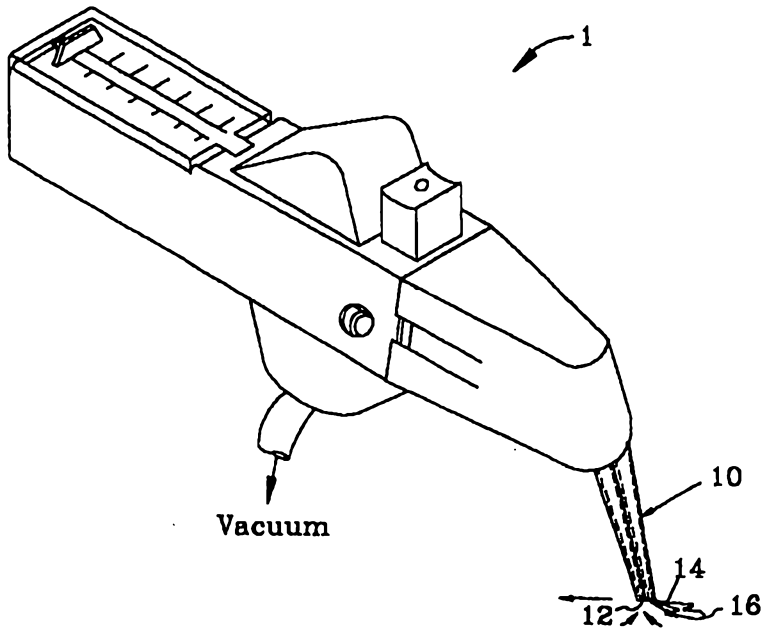

(57) Abstract

A medical fluid applicator (1) for dispensing a fluid onto biological tissues in tissue adhesive or sealant applications includes a dispensing pathway (5) with an audible loudness indicator (200) that signals the cumulative amount of fluid delivered by varying the pitch or tone of audible signals emitted at discrete volumetric increments. A suction pathway (7) is also included for applying vacuum pressure to the applicator tip (10) contemporaneous with the fluid application. The medical fluid applicator (1) further includes a clearing pathway (8) for retrogradely withdrawing coagulated mixed fluids, such as mixed two-part tissue adhesives from the applicator tip (10).

FLUID APPLICATOR FOR DISPENSING MEASURED QUANTITIESWITH USE OF CONTROLLED SUCTION

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 MEDICAL SUCTIONING APPARATUS AND METHODS OF USE, the disclosure of which copending international application is hereby incorporated herein by reference thereto.

TECHNICAL FIELD

The invention is a medical device which combines controlled dispensing of liquid or semiliquid substances with controlled suction. More specifically, the invention is a tissue adhesive applicator which selectively provides suction at the applicator tip during or immediately prior to adhesive application, or for clearing coagulated adhesive from the applicator tip.

BACKGROUND

Various known devices provide for the controlled dispensing of medical fluids. Furthermore, some are adapted to provide suction as well as irrigation at the dispensing tip. The suction is generally suitable for the removal of fluids during surgical procedures.

Examples of medical devices which are adapted to dispense fluid as well as provide vacuum at the working tip are disclosed in U.S. Patent Nos.: 3,065,749; 3,469,582; 4,397,640; 4,573,979; 4,617,013; 4,696,669; 4,708,717; 4,776,840; 4,857,047; 5,061,180; and 5,226,877. Some of these devices have a suction pathway which is distinct from their dispensing pathway, such as those disclosed in U.S. Patent Nos.: 3,065,749; 4,397,640; 4,573,979; 4,617,013; 4,696,669; 4,708,717; 4,857,047; 5,061,180; 5,226,877. Alternatively, some use the same pathway to either provide suction or dispense fluid, such as the devices disclosed in U.S. Patent No. 3,469,582 and 4,776,840.

Referring to U.S. Patent No. 4,776,840 to Freitas, a device is disclosed which has a suction outlet adjacent to a dispensing outlet which may also provide suction in parallel to the suction outlet. In order to provide suction at the working tip, the user depresses a plunger which connects the vacuum source to the dispensing outlet pathway in addition to the suction pathway. In

contrast, if the user desires to dispense fluid, the user pulls a trigger switch which is in communication with a piston. As the trigger is displaced, the piston is displaced and pushes fluid through a check valve leading to the dispensing outlet pathway.

In addition, devices adapted to dispense tissue adhesives or sealant are disclosed in U.S. Patent Nos.: 4,040,420; 4,359,049; 4,735,616; 4,874,368; 4,978,336; 5,116,315; 5,226,877; 5,368,563; 5,474,540; and 5,605,541. Typically, these known devices have two self-contained fluid reservoirs. Each reservoir has an outlet passageway which may lead to a common passageway in which the fluids mix. In many tissue adhesive applications, a fibrinogen solution is mixed with a thrombin solution to start the clotting process and form the physiological adhesive or sealant. Often, the mixture that remains in the mixing passageway commonly causes clogging of the dispensing tip. To overcome this obstacle, some devices have been developed to spray the independent components of a two part biological adhesive so that mixing occurs in the spray between a device nozzle head and the tissue. Examples of such spraying devices are disclosed in U.S. Patent Nos. 5,368,563 and 5,605,541.

Finally, disclosed suction and medical dispensing devices provide very limited volume indicators, such as visual volume indicators on the working device which require the user's attention to be diverted from the working area of fluid dispensing. An alternative volume indication mechanism is disclosed in U.S. Patent No. 5,226,877 to Epstein. Epstein discloses a medical dispensing device that has an audible loudness indicator which provides discrete audible "clicks" at predetermined incremental volumes of fluid delivery. However, this beneficial indicator does not audibly indicate the cumulative volume of fluid dispensed, but instead requires a user to remember the number of clicks.

There is still a need for an audible loudness indicator which emits audible signals to a user that indicate the cumulative volume of fluid dispensed at each incremental volume of fluid delivery.

There is also still a need for an apparatus and method for withdrawing a cast of cured tissue adhesive or other congealing fluid from the dispensing conduit in the tip of a medical fluid applicator.

SUMMARY OF THE INVENTION

The present invention is a medical fluid applicator assembly which includes a dispensing

assembly in combination with a suction assembly.

In one aspect of the invention, a dispensing assembly includes an audible loudness indicator which signals the cumulative volume of fluid dispensed by changing the pitch or loudness of an audible tone produced at predetermined volumetric increments.

In one variation of this fluid dispensing assembly, the audible loudness indicator includes a rack and pawl assembly which has a plurality of teeth with variably positioned regions on the rack. The varied teeth produce incremental tones with changing pitch when the various regions translate across a striker.

In another variation of this fluid dispensing assembly, each of two reservoirs contains one component of a two-part fluid to be mixed prior to delivery. The reservoirs are coupled to a common portion of a dispensing conduit in a shaped tip applicator. An actuator delivers each adhesive component from its respective reservoir, into the dispensing conduit where they are mixed, and distally out of the applicator tip. Further to this variation, one chamber preferably houses a fibrinogen-containing fluid and the other chamber houses a fluid containing a catalyst for coagulating the fibrinogen, such as a thrombin-containing fluid.

In another aspect of the invention, a medical suction device assembly includes a vacuum conduit, a suction conduit, a vent conduit, and a valve manifold adapted to adjust the fluid communication between the vacuum conduit and the suction conduit while simultaneously and inversely adjusting the proportion of vacuum applied to the vent conduit. In this arrangement a controllable range of applied vacuum at the suction conduit may be selected by varying the proportion of vacuum pressure which is applied between the vent and the suction conduit.

In one variation of this medical suction device assembly, the valve manifold is engaged within a valve housing which includes a vent port in communication with the vent conduit, a suction port in communication with the suction conduit, and a vacuum port in communication with the vacuum conduit. The valve manifold has a valve wall forming a valve chamber and which includes a vacuum aperture, a suction aperture, and a vent aperture. The suction and vent apertures are adapted such that, by varying the positioning of the valve manifold between selected positions within the valve housing, they translate across the suction port and vent port, respectively, at the same time and while the valve vacuum aperture is registered with the

vacuum port.

In a further variation, each of the suction and vent apertures also has a non-uniform cross section taken along an elongate axis thereof which is aligned with the axis of motion for translating across the corresponding valve housing port. Each of these two apertures is further positioned an the valve manifold in a relatively reciprocal orientation relative to the other, such that when the valve manifold is adjusted to register an increased-diameter portion of one aperture with its corresponding port, the other aperture has a decreased-diameter portion in registry with the other corresponding port.

In another aspect of the invention, a combination dispenser/suction device assembly includes an applicator tip portion with a suction conduit and a dispensing conduit. A valve manifold is adapted to shuttle an applied vacuum source between the suction conduit and the dispensing conduit.

In another aspect of the invention, an applicator/suction device assembly includes a dispensing pathway which is coupled at one end to at least one fluid reservoir and at the other end to a dispensing conduit in an applicator tip portion of the device. The dispensing conduit terminates distally at a tip dispensing aperture. A valve manifold is adapted to selectively interrupt the dispensing pathway by isolating the fluid reservoir from the dispensing conduit, and is further adapted to fluidly couple the dispensing conduit to a vacuum conduit which is further coupled to a vacuum source.

In a further variation of this applicator/suction device assembly, the applicator tip portion also includes a suction conduit which terminates in a tip suction aperture. The valve manifold of this variation is adapted to selectively direct applied vacuum from the vacuum conduit to either of the suction or dispensing conduits in the applicator tip portion. The valve manifold is adjustable from a first position, wherein the vacuum conduit communicates with the suction conduit and is isolated from the dispensing conduit, to a second position wherein the vacuum conduit communicates with the dispensing conduit and is isolated from the suction conduit.

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 body 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 body 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 body portion of the medical fluid applicator of Figure 1.

Figure 16 is a perspective view of the dispenser assembly of Figure 15 with the body 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 body 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.

Figure 21 is a perspective view of a lid portion of a modified embodiment of filling dispenser shown inverted; and

Figure 22 is a perspective view of a mating base portion of the modified embodiment of fillingdispenser.

DETAILED DESCRIPTION OF THE INVENTION

The present invention will be illustrated by means of a preferred embodiment shown in the drawings, from which it is to be understood that the medical fluid applicator assembly of the present invention includes a combination of features. One beneficial feature of the current invention is a dispensing assembly which includes a fluid dispensing pathway and an actuating assembly which is closely integrated with an audible loudness indicator that audibly signals the cumulative volume of tissue dispensed. Another beneficial feature of the present invention is a suction assembly which includes a means for shuttling applied vacuum from a suction pathway, which includes a suction conduit at the applicator tip, to a clearing pathway, which couples to the dispensing conduit at the applicator tip. Further to the suction assembly, a further beneficial feature is provided in a valve manifold which allows for selectively controlling the level of applied vacuum at the suction conduit in the applicator tip. Still a further beneficial feature is provided in a filling dispenser assembly which has a keyed coupling with a body such that multiple fluid reservoirs in the body may be filled with isolated fluids from the filling dispenser in a predetermined arrangement.

While the term "fluid" as used in physics may comprise any matter in the liquid or gaseous state, the applicators described herein, aside from their described aspirator functions are not specifically intended for dispensing gases via what ae described as "fluid pathways", or "fluid dispensing pathways" and the like. (However the suction pathway can be used to dispense pressurized air or other gases, if desired.) Accordingly, the use of the term "fluid" herein is intended to embrace flowable, non-gaseous materials that can usefully be dispensed from the described applicators, including besides liquids and liquid solutions, dispersions, gels, slurries and the like, being suspensions of solid particles in a liquid phase, thixotropic and semi-solid materials. Those skilled in the art will understand that more viscous fluids may require

relatively large passageways and ports, while less viscous fluids may require better seals to prevent leakage.

Detailed description of these and other beneficial features of the present invention is provided below in reference to the various figures as follows. Figures 1-2C provide various perspective views of the overall medical fluid applicator assembly of the present invention. Figure 3 provides an overview of the removably engageable body 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 aspects 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 present invention.

Referring to a general overview of the device by reference to Figures 1-2C, medical fluid applicator assembly 1 is shown in overview fashion 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 a vacuum source, 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 surface.

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.

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. As would be apparent to one of ordinary skill, the remaining detailed disclosure below describes additional novel operating features of the present invention, in addition to the features shown in Figure 1 which provide for tissue preparation contemporaneous with fluid application.

As shown in Figure 3, the inner workings of medical fluid applicator assembly 1 are divided between body portion 2 and applicator portion 3 which is removably engageable to body portion 2. As is apparent to one of ordinary skill by reference to Figure 3, when applicator portion 3 and body 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 of the current invention are generally shown in Figures 3-7 to include an overall dispensing pathway 5, the proximal portions of which being shown in detail in Figures 4A-C, and also 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 variously throughout Figures 3-4C, proximal portions of that pathway within the body 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 mixed 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 mixed conduit 92, which extends distally therefrom through applicator tip 10 where it terminates at tip dispensing aperture 14. At the point where branch conduits 82, 84 merge, distally flowing fluids impinge directly upon one another, at approximatley 180°, causing apposite mixing.

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 body/applicator portion interface creates interface fluid dispensing pathway 5 which includes reservoirs 52,54, supply conduits 56,58, branch conduits 82,84, and mixed 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 the fluid dispensing pathway 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 the fluid dispensing pathway.

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 pawl 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 loudness 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 loudness indicator 200 is herein described also by reference to Figure 3, as well as to Figures 5 and 6. Audible loudness 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 loudness or volume of 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 dispenser assembly of 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 body portion and into the applicator portion through the 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 body. 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 body portion 2 are shown in Figure 5 to include a vacuum conduit 250 which is selectively coupled to vacuum coupling ports 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 body 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 body suction port 256 with applicator suction port 258, and similarly coupling and aligning body clearing port 257 with applicator suction port 259 Figure 3 to form one contiguous channel between the valve housing and the mixed 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 mixed 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 ports 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 slideable 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 ports 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.

Further to the design of valve stem 310 and its apertures as shown in Figures 9A-D, each of suction aperture 314 and clearing aperture 316 is shown to be a non-circular shaped opening having an elongate axis aligned with the longitudinal axis of valve stem 310 shown in dashed line in Figure 9E, a wide axis, and a short axis, such as are shown at long axis "L", wide axis "W", and short axis "S" for clearing aperture 316. Wide axis "W" has a larger cross-sectional area than the cross-sectional area of short axis "S" in the perpendicular plane to long axis "L". For the purpose of further understanding, this described shape may be considered a "tear-drop" shape, or a "diminished elliptical" shape. In addition, the wide and short axes of clearing aperture 316 are provided in an inverse reciprocal orientation along the longitudinal axis relative to the respective orientation of suction aperture 314. The primary purpose for this inverse reciprocal orientation of long and short axis for suction aperture 314 and clearing aperture 316 is in one particular mode of operation wherein clearing aperture 316 is used as a vent in a venturi valve-role for controlling the level of suction applied to suction conduit 270, as will be developed further below with reference to Figures 13A-B. Nevertheless, it should be apparent to one of ordinary skill that the short axis leads the wide axis for suction aperture 314

during a downward vertical motion of valve stem 310 along its longitudinal axis, while the wide axis instead leads the short axis for clearing aperture 316 during that range of motion.

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 shuttle valve 350, 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 medical fluid applicator of the current invention. Shuttle valve 350 functions to selectively and alternatively 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 function of the current 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 the shuttle valve 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 suction valving components of the present invention , including the valve manifold and the shuttle manifold, 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 mixed 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 mixed 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 mixed 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 mixed 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 in performing applied suction to suction conduit 260 is further shown schematically by reference to Figures 13A-B. 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 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 to a suctioning position within the valve housing which is somewhere between the resting or venting position such as in Figures 12A or 13A and the first suction position such as in Figure 13B. It is to be understood by one of ordinary skill that, 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. 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.

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.

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 the branch conduits 82,84 and also clearing conduit 270 are shown to include 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 of 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 the mixed fluid from the applicator tip region.

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 branched channel 82 or branched 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 mixed 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 mixed 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 slideable 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 mixed 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 mixed 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 mixed 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 slideable 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 aspect of the current invention, body portion 2 of medical fluid applicator 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 body 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 414,424 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 body via keyed coupling 430.

As shown in overview in Figure 16, keyed coupling 430 is adapted to engage body portion 2 such that the fluid reservoirs of the body 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 body 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 body 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.

Figures 21 and 22 depict a modified embodiment of filling dispenser 440 which is generally similar to that shown in Figures 15-17 and is provided with additional sealing means against leakage of fluid out of individual reservoirs. The filling dispenser comprises a base portion 442 (Figure 22) with D-shaped fluid reserviors 444 and 446 and a mating lid portion 448 (Figure 21 in inverted position) adapted to mate with an applicator body in the same way as the Figures 15-17 embodiment. Reservoirs 444 and 446 are separated by divider 450 with a cutout 452 and each reservoir has a continuous, upstanding, peripheral seals 454. Sockets 456 receive pins 458 in lid 448 providing guides, additional keying and greater rigidity. Seals 454 create a double track along divider 450.

Lid portion 448 has D-shaped recesses 460 to matingly receive seals 454 . Thus lid portion 448

is thus partially received in base portion 442 and is a tight sealing fit therewith.

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 body 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 body 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 body 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 body 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 mixed 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 mixed 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 mixed 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 body 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 mixed 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 mixed 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 alternatives 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.

What is claimed is:

1. A manually operable suction-enabled fluid sealant applicator (1) for dispensing sealant on to a work surface, the applicator (1) comprising:

a) a fluid sealant dispensing pathway (5); and

b) a suction pathway (7, Fig. 3; 6, Fig. 12B) connectable to a suction source;

characterized by further comprising a suction control valve (300) operable to connect the suction pathway (7, Fig. 3; 6, Fig. 12B) with the fluid dispensing pathway (5) to apply suction to, and remove undesired material from, the fluid sealant dispensing pathway (5).

2. A fluid sealant applicator (1) according to claim 2 **characterized by** comprising a fluid sealant source connectable with the dispensing pathway (5) and a valve (350) to disconnect the fluid sealant dispensing pathway (5) from the fluid sealant source when the suction pathway (7, Fig. 3; 6, Fig. 12B) is connected with the fluid dispensing pathway (5).

3. A fluid sealant applicator (1) according to claim 1 or 2 **characterized in that** the suction pathway (7, Fig. 3; 6, Fig. 12B) comprises a suction dispensing aperture (12) enabling suction to be applied to the work surface.

4. A fluid sealant applicator (1) according to claim 3 **characterized in that** the suction control valve (300) is operable to apply suction to the suction dispensing aperture (12) and to disconnect the suction dispensing aperture (12) from the suction source when suction is applied to the fluid dispensing aperture.

5. A fluid sealant applicator (1) according to claim 1, 2 or 4 **characterized in that** the fluid sealant dispensing pathway (5) connects with multiple sources (52-54) of sealant components and mixes the sealant components to form a mixed fluid sealant.

6. A fluid sealant applicator (1) according to claim 1, 2 or 4 **characterized in that** the fluid sealant dispensing pathway (5) has a cross-sectional area which increases and does not decrease in a direction from a point of dispensing to a point of connection with the suction pathway (7, Fig. 3; 6, Fig. 12B) to facilitate removal of undesired solids therefrom.

7. A medical fluid applicator (1), comprising:

a) a housing with an applicator (1) tip having a tip dispensing aperture;

b) a fluid dispensing pathway (5) within said housing comprising at least two fluid reservoirs (52,54) and a dispensing conduit leading from the fluid reservoirs (52,54) to the tip dispensing aperture; and

c) a suction pathway (7, Fig. 3; 6, Fig. 12B) connectable to a vacuum source;

characterized by further comprising

d) a clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B) connectable to the vacuum source via the suction pathway (7, Fig. 3; 6, Fig. 12B);

e) a control valve assembly coupled to the fluid dispensing pathway (5) and to the clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B) and movable from a first, dispensing position wherein the dispensing conduit is in fluid communication with the fluid reservoirs (52,54) and is substantially isolated from the clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B), to a second, clearing position wherein at least a distal portion of the dispensing conduit is substantially isolated from the fluid reservoirs (52,54) and is in fluid communication with the clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B).

8. A medical fluid applicator (1) according to claim 7 **characterized by** comprising a manually operable dispensing actuator (105) to dispense fluid contained in the fluid reservoirs (52,54) through the dispensing conduit when the valve assembly is in the first dispensing position, wherein in the second, clearing position of the control valve assembly, the distal portion of the dispensing pathway (5) is connectable with the vacuum source to clear the distal portion of its contents.

9. A medical fluid applicator (1) according to claim 8 **characterized in that** one of said fluid reservoirs (52,54) contains a first fluid; and the other of said fluid reservoirs contains a second fluid and **in that** operation of the actuator (105) causes said first and second fluids to flow distally from the fluid reservoirs (52,54) and to form a mixture within the dispensing conduit.

10. A medical fluid applicator (1) according to claim 7 **characterized in that** said first fluid is a fibrinogen-containing fluid and said second fluid contains a catalyst or activator for coagulating said first fluid.

11. A medical fluid applicator (1) according to claim 10 **characterized in that** at least one

of the catalyst or activator comprises thrombin.

12. A medical fluid applicator (1) according to claim 7 **characterized in that** at least one of said first and second fluids comprises a biologically or pharmacologically active agent.

13. A medical fluid applicator (1) according to claim 7 **characterized in that** the dispensing conduit comprises:

i) a branched portion having two branch conduits, each branch conduit being in fluid communication with one of the fluid reservoirs (52,54); and

ii) a mixing portion having a mixing conduit which terminates distally in the tip dispensing aperture;

wherein when the control valve assembly is in the first dispensing position the mixing conduit is isolated from the clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B) and is in fluid communication with the branch conduits so that fluid from the branch conduits is mixed in the mixing conduit prior to discharge through the tip dispensing aperture, and when the control valve assembly is in the second clearing position, the mixing conduit is in fluid communication with the clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B) and is isolated from the branch conduits.

14. A medical fluid applicator (1) according to claim 7 **characterized in that** the housing further comprises:

i) a body portion which includes the fluid reservoirs (52,54), the dispensing actuator (105), the vacuum conduit, and a supply conduit which fluidly couples each fluid reservoir with one of two supply ports; and

ii) an applicator (1) portion which includes the applicator (1) tip, the dispensing conduit, and the valve assembly, each said branch conduit terminating proximally in one of two proximal dispensing ports;

and in that the applicator (1) portion is removably engageable with the body to put the proximal dispensing ports in fluid communication with the supply ports.

15. A medical fluid applicator (1) according to claim 13 **characterized in that** the clearing conduit and the mixing conduit are coupled to form a continuously tapered bore with a distally reducing inner diameter.

16. A medical fluid applicator (1) according to claim 7 **characterized in that** the valve assembly further comprises a clearing valve portion coupled to an inner lumen of the clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B) so that, in the first, dispensing position, the clearing valve portion substantially isolates the mixing conduit from the clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B) and, in the second clearing position, the clearing valve portion couples the mixing conduit and the clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B) to allow for fluid communication therebetween.

17. A medical fluid applicator (1) according to claim 16 **characterized in that** the control valve assembly further comprises two dispensing valve portions, each being coupled to an inner lumen of one of the branch conduits so that, in the first, dispensing position, the branch conduit is in fluid communication with the mixing conduit and, in the second, clearing position, the branch conduit is substantially isolated from the mixing conduit.

18. A medical fluid applicator (1) according to claim 17 **characterized in that** each branch conduit has a slotted portion to slidably receive one of the dispensing valve portions, the clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B) has a slotted portion to receive the clearing valve portion and each of the dispensing valve portions and the clearing valve portion has both a flow aperture and a closed portion wherein in the first, dispensing position, the flow aperture of each dispensing valve portion registers with the slotted portion of a branch conduit to allow flow therethrough, and the closed portion of the clearing valve portion registers with the slotted portion of the clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B) to substantially obstruct flow therethrough, and wherein, in the second clearing position, the closed portion of each dispensing valve portion registers with the slotted portion of a branch conduit to substantially obstruct flow therethrough, and the flow aperture of the clearing valve portion registers with the slotted portion of the clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B) to allow flow therethrough.

19. A medical fluid applicator (1) according to claim 7 **characterized by** further comprising

a clearing conduit coupled to at least a distal portion of the dispensing conduit and adapted to form at least in part the clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B);

a suction conduit adjacent the dispensing conduit and terminating at the applicator (1) tip in a tip suction aperture;

a vacuum conduit adapted to couple to a vacuum source; and

a valve manifold coupled to the clearing, suction, and vacuum conduits and which is adjustable from a first suction position to a second manifold clearing position, wherein

in the first suction position the vacuum conduit is substantially isolated from the clearing conduit and is in fluid communication with the suction conduit to form a suction pathway (7, Fig. 3; 6, Fig. 12B), and

in the second manifold clearing position the vacuum conduit is substantially isolated from the suction conduit and is in fluid communication with the clearing conduit to form the clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B).

20. A medical fluid applicator (1) according to claim 19 **characterized in that** the housing further comprises:

a body portion which includes the fluid reservoirs (52,54), the dispensing actuator (105), the vacuum conduit, and the valve manifold, the body portion further including a supply conduit which fluidly couples each fluid reservoir with one of two supply ports; and

an applicator (1) portion which includes the applicator (1) tip, the dispensing conduit, the suction conduit, the clearing conduit, and the valve assembly,

the dispensing conduit having a mixed portion and two branched channels extending proximally therefrom and terminating proximally in two proximal dispensing ports, the suction conduit terminating proximally in a proximal suction port, and the clearing conduit terminating proximally in a proximal clearing port,

wherein the applicator (1) portion is removably engageable with the body portion such that when the applicator (1) and body portions are engaged the proximal dispensing ports are in fluid communication with the supply ports and such that the proximal suction port and the proximal clearing port are coupled with the valve manifold.

21. A medical fluid applicator (1) according to claim 20 **characterized by** comprising

a valve housing which houses the valve manifold and which includes a vacuum aperture in communication with the vacuum conduit, a suction aperture in communication with the suction conduit, and a clearing aperture in communication with the clearing conduit; and

the valve manifold further comprises a valve wall which forms a valve chamber that communicates externally of the valve wall through a valve vacuum port, a valve suction port, and a valve clearing port, wherein

in the first suction position the valve vacuum port and valve suction port are aligned with the vacuum and suction apertures, respectively, to form a suction pathway (7, Fig. 3; 6, Fig. 12B), and the valve clearing port is out of alignment with the clearing aperture with the valve wall substantially isolating the clearing conduit from the suction pathway (7, Fig. 3; 6, Fig. 12B), and

in the second manifold clearing position the valve vacuum port and valve clearing port are aligned with the vacuum and clearing apertures, respectively, to form the clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B), and the suction port is out of alignment with the suction conduit with the valve wall substantially isolating the suction aperture from the clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B).

22. A medical fluid applicator (1) according to claim 20 **characterized by** comprising

a valve actuator which is coupled to both the valve assembly and also to the valve manifold, the valve actuator being adjustable from a first actuated position, wherein the valve assembly is in the first, dispensing position and the valve manifold is in the first suction position, to a second actuated position, wherein the valve assembly is adjusted to the second clearing position and the valve manifold is adjusted to the second manifold clearing position.

23. A medical fluid applicator (1) according to claim 14 **characterized by** comprising

a filling dispenser having two filling chambers, each containing one part of a two-part tissue adhesive and having a filling port within a keyway adapted to couple to the body portion in a predetermined orientation such that each of the filling ports is coupled to a predetermined one of the supply ports; and

a filling actuator adapted to provide suction at each of the supply ports,

whereby coupling the supply port with the filling dispenser in the predetermined orientation the contents of the filling chambers may be withdrawn therefrom, through the dispenser ports and respectively coupled supply ports, and into the predetermined reservoirs (52,54).

24. A medical fluid applicator (1) according to claim 23 **characterized in that** one filling chamber contains a thrombin-containing liquid and the other filling chamber contains a fibrinogen-containing liquid.

25. A method for clearing the contents from the tip of a medical fluid applicator (1) assembly having at least two fluid reservoirs (52,54) in fluid communication with a dispensing conduit which terminates at a tip dispensing aperture in an applicator (1) tip characterized by comprising the steps of:

a) substantially isolating each fluid reservoir from fluid communication with the dispensing conduit;

b) fluidly coupling a clearing conduit into fluid communication with the dispensing conduit;

c) applying suction to the dispensing conduit through the clearing conduit to retrogradedly withdraw the contents of the dispensing conduit through the clearing conduit.

26. A method according to claim 25 characterized by further comprising the step of:

d) selectively adjusting applied suction from a suction conduit, which terminates in a tip suction aperture adjacent the tip dispensing aperture in the applicator (1) tip, to the clearing conduit.

27. A method according to claim 25, characterized by further comprising the step of:

filling the dispensing conduit with each part of a two part tissue adhesive from each reservoir to thereby form a mixed tissue adhesive.

28. A method for clearing the contents from the tip of a medical fluid applicator (1) assembly having at least one fluid reservoir which communicates with a dispensing conduit to form a fluid dispensing pathway (5), the dispensing conduit having a tapered inner bore with a distally reducing inner diameter which terminates in a tip dispensing aperture in an applicator tip characterized by comprising the steps of:

introducing a fluid contained within the fluid reservoir into the dispensing conduit;

forming an occlusive cast within the dispensing conduit with the fluid;

retrogradedly withdrawing the occlusive cast from the dispensing conduit and removing it from the fluid dispensing pathway (5).

29. A method of applying a coagulable sealant comprising dispensing the sealant through a dispensing tube supported from a hand held applicator (1) to a work surface characterized by intermittently applying suction to the dispensing tube to remove undesired material

therefrom.

30. A method according to claim 29 characterized by being a surgical method of sealing tissue, wherein the sealant is a biological tissue sealant.

31. A medical fluid applicator (1) assembly for dispensing a two-part tissue adhesive onto animal tissue, comprising:

a housing with an applicator (1) tip;

two fluid reservoirs (52,54) within the housing;

a dispensing conduit in fluid communication with the reservoirs (52,54) and having a mixing portion which terminates at the applicator (1) tip in a tip dispensing aperture; and

dispensing means for actuating flow of a fluid from each reservoir into dispensing conduit to form a mixture of the fluids in the mixing portion of the dispensing conduit which flows out the tip dispensing aperture; characterized by further comprising

clearing means for retrogradedly withdrawing and clearing the mixture from the mixing portion of the dispensing conduit while isolating the fluid reservoirs (52,54) from the mixing portion.

32. A medical fluid applicator (1) assembly according to claim 31, **characterized in that** the fluid reservoirs (52,54) further comprise tubular chambers, and wherein the dispensing means comprises an actuating means with two plungers which are each adapted to slidably engage an interior bore within one of the tubular chambers and advance within that interior bore to force fluids contained therein distally through the dispensing conduit.

33. A medical fluid applicator (1) assembly according to claim 31 **characterized in that** the clearing means comprises

a clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B) adapted to couple with a vacuum source; and

a first valve means adapted to selectively couple the clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B) in fluid communication with the mixing portion of the dispensing conduit while substantially isolating the fluid reservoirs (52,54) from that mixing portion.

34. A medical fluid applicator (1) assembly according to claim 31 **characterized by** further comprising:

mixing means for mixing the contents of each reservoir prior to dispensing through the mixing portion of the dispensing conduit.

35. A medical fluid applicator (1) assembly according to claim 34 **characterized in that** the mixing means further comprises

a branched portion of the dispensing conduit which includes two branch conduits each being in fluid communication with one of the fluid reservoirs (52,54); and

a mixing conduit in fluid communication with each of the branch conduits and which comprises at least in part the mixing portion of the dispensing conduit.

36. A medical fluid applicator (1) assembly according to claim 31 **characterized by** further comprising suction means for applying suction at a tip suction aperture located adjacent the tip dispensing aperture at the applicator (1) tip.

37. A medical fluid applicator (1) assembly according to claim 36 **characterized by** further comprising a second valve means adapted for selectively applying suction from a vacuum source either to the tip suction aperture or to the dispensing conduit.

38. A medical fluid applicator (1) assembly according to claim 37 **characterized in that** the clearing means comprises

a clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B) adapted to couple with a vacuum source; and

a valve assembly adapted to selectively couple the clearing pathway (8, Fig. 3; 7, Fig. 12C; 270, Fig. 14B) in fluid communication with the mixing portion of the dispensing conduit while substantially isolating the fluid reservoirs (52,54) from that mixing portion.

39. A medical fluid applicator (1) assembly according to claim 31 **characterized by** further comprising:

filling means for filling each of the fluid reservoirs (52,54) with a predetermined part of a two-part tissue adhesive.

40. A medical fluid applicator (1) assembly according to claim 33 **characterized in that** the shuttle means is disposed in the mixing head.

41. A medical fluid applicator (1) assembly according to claim 32 **characterized in that** the actuating means is adapted to dispense fluid from the reservoirs (52,54) in discrete incremental volumes.

42. A medical fluid applicator (1) assembly according to claim 41 **characterized by** further comprising an audible loudness indicator means for providing an audible signal at each increment of fluid delivery.

43. A medical fluid applicator (1) assembly according to claim 42 **characterized in that** the audible loudness indicator means includes a means for varying the audible signal in either pitch or loudness according to the cumulative volume dispensed over a plurality of incrementally dispensed volumes.

44. A medical fluid applicator (1) assembly according to claim 40 **characterized in that** the actuating means comprises a rack (130) and pawl (120).

45. A medical fluid applicator (1) assembly comprising:

a housing with a proximal end, a distal end, and an applicator (1) tip at the distal end;

a fluid dispensing pathway (5) within the housing and which includes a fluid reservoir and a dispensing conduit which terminates at the applicator (1) tip in a tip dispensing aperture; and

an actuating assembly at least in part within the housing and being adapted to dispense fluid contained in the fluid reservoir distally therefrom, through the dispensing conduit, and out the tip dispensing aperture in predetermined, discrete incremental volumes; **characterized by** further comprising

an audible loudness indicator engaged within the housing and adapted to emit tones which are discrete and audible with each incremental volume of fluid delivered by the actuating assembly, wherein the tones vary in either pitch or loudness in relation to the cumulative volume of fluid dispensed.

46. A medical fluid applicator (1) assembly according to claim 45, **characterized in that** the audible loudness indicator is coupled to the actuating assembly.

47. A medical fluid applicator (1) assembly according to claim 46, **characterized in that**

the actuating assembly includes a plunger coupled to an interior lumen of the fluid reservoir and being adapted to pressurize that fluid reservoir by a rack-and-pawl mechanism, the rack-and-pawl mechanism further comprising:

an actuating trigger (105) having a range of motion between a resting trigger position and an actuated trigger position and also having a spring bias toward the resting position;

a rack (130) within the housing with a longitudinal axis and which is moveable within the housing in the direction between the proximal and distal ends, the rack (130) further having a plurality of actuating teeth (132) spaced along the longitudinal axis, the rack (130) being engaged to; and

a pawl (120) with a first end engaged to the actuating trigger (105) and an opposite second end with a hook adapted to rest within the space between adjacent actuating teeth (132), the hook further being adapted to engage the actuating teeth (132) when the pawl (120) is advanced in a distal direction relative the longitudinal axis and also being adapted to slidably advance over the actuating teeth (132) when the pawl (120) is advanced proximally relative to the rack (130)'s longitudinal axis;

wherein in the resting trigger (105) position the pawl (120) has a proximal resting position within the housing, and when the trigger (105) is adjusted from the resting trigger position to the actuated trigger position the rack (130) is actuated distally by the hook for a predetermined distance, such that the plunger translates distally within the reservoir to dispense a predetermined volume of fluid, and

wherein when the trigger (105) is adjusted from the actuated trigger position to the resting trigger position, the pawl (120) slidably advances proximally over the actuating teeth (132) to return to the proximal resting position without adjusting the positioning of the rack (130) or the plungers.

48. A medical fluid applicator (1) assembly according to claim 47 **characterized in that** the audible loudness indicator further comprises

a plurality of teeth (132) on the rack (130) which are spaced along the longitudinal axis at intervals corresponding to predetermined incremental fluid delivery volumes; and

a striker (210) engaged within the housing and having a plurality of striker arms (220), each said striker arm (220) being adapted to emit a tone upon striking a tooth (132), the plurality of striker arms (220) being positioned relative to the teeth (132) such that varying combinations of the striker arms (220) are struck by the teeth (132) at different positions along the longitudinal axis of the rack (130).

49. A medical fluid applicator (1) assembly according to claim 47, **characterized in that** the teeth (132) are spaced along the longitudinal axis with varied axial positions and wherein the striker arms (220) are spaced along an axial plane such that each tooth (132) is adapted to strike a predetermined combination of the striker arms (220).

50. A medical fluid applicator (1) assembly according to claim 49, **characterized in that** the striker arms (220) have varied lengths.

51. A medical fluid applicator (1) assembly of claim 49, **characterized in that** the striker arms (220) have varied thicknesses.

52. A medical fluid applicator (1) assembly according to claim 49, **characterized in that** the striker arms (220) comprise different materials.

53. A biological fluid dispensing device comprising:

a) a dispenser body intended to be held in the hand of a user;

b) a reservoir supported by said dispenser body and having an internal volume for containing biological fluid to be dispensed; and

c) a driver mechanically coupled to said reservoir for movement within a range of driver positions with respect to said reservoir and cooperating with said reservoir to vary said internal volume in response to changes in driver position;

characterized by further comprising

d) an audible indicator coupled to said driver for emitting, in response to changes in driver position, an audible sound indicating the position of said driver and the corresponding magnitude of said internal volume.

54. A filling dispenser assembly for use in filling a body used in medical fluid delivery, comprising a housing with first and second filling reservoirs (52,54) which are isolated from each other and separated by a barrier within the housing **characterized by** the filling reservoirs (52,54) including first and second dispenser coupling ports, respectively, which are adapted to couple with a supply port of the body; and **by** the filling dispenser assembly further comprising a keyway coupler for engaging a coupling end of a body in a predetermined orientation relative to the dispenser coupling ports, wherein when the body is

engaged with the keyway coupler at least one supply port on the body is coupled with a predetermined one of the first and second dispenser coupling ports.

55. A filling dispenser assembly according to claim 54 **characterized by** further comprising:

a medical fluid applicator (1) having a body portion with first and second supply ports which are coupled to first and second fluid reservoirs (52,54), respectively,

the body portion further having a keyed end which includes the supply ports, the keyed end being adapted to engage the keyway coupler such that the first and second supply ports can engage only the first and second dispenser coupling ports.

56. A filling dispenser assembly according to claim 54, **characterized in that** the first filling reservoir is filled with a first fluid and the second filling reservoir is filled at least partially with a second fluid.

57. A filling dispenser assembly according to claim 54, **characterized in that** the first filling reservoir is filled with a first part of a two-part tissue adhesive or sealant, and the second filling reservoir is filled with the second part of the two-part tissue adhesive or sealant.

58. A filling dispenser assembly according to claim 54, **characterized in that** the first filling reservoir is filled with a thrombin-containing fluid, and the second filling reservoir is filled with a fluid which contains a catalyst or activator which activates a clotting response in the thrombin-containing fluid of the first filling reservoir.

59. A manually actuated sealant applicator (1) for dispensing a mixed output of at least two fluid sealant components capable, when mixed together, of generating a solid sealant product, the applicator (1) comprising:

a) a mixing zone for mixing said at least two fluid sealant components; and

b) at least two fluid sealant component delivery passages (5-5, 82-84) connecting with the mixing zone to deliver at least two flows of the respective sealant components to the mixing zone;

characterized in that the fluid sealant component delivery passages (5-5, 82-84) connect with the mixing zone with orientations that directly oppose each flow to the other to enhance

mixing of the fluid components.

60. A manually actuated sealant applicator (1) according to claim 59 **characterized by** comprising a manually movable control member (15, 345) operable to clear undesired solid material from the mixing zone.

61. A manually actuated sealant applicator (1) according to claim 60 **characterized in that** the applicator (1) comprises a hand held housing housing the mixing zone and the fluid component delivery passages (5-5, 82-84) and **in that** the control member (15, 345) is accessible externally of the housing.

62. A manually actuated sealant applicator (1) according to claim 61 **characterized by** comprising a clearing mechanism (270, 350) operated by the control member (15, 345) to clear the mixing zone.

63. A manually actuated sealant applicator (1) according to claim 62 **characterized in that** the clearing mechanism (270, 350) comprises a clearing structure (270) activatable to clear the mixing zone and a valve (350) to control flow of the fluid components through the fluid component delivery passages (5-5, 82-84) and to activate the clearing structure (270) wherein the valve (350) is movable by operation of the control member (15, 345) simultaneously to prevent fluid component flow and to activate the clearing structure (270).

64. A manually actuated sealant applicator (1) according to claim 59, 60, 61 or 62 **characterized in that** the fluid sealant components are components of a biologically acceptable fibrin sealant.

65. A manually actuated sealant applicator (1) having a sealant dispensing pathway **characterized by** comprising a clearing mechanism (270, 350) and a manually movable control member (15, 345) operable to actuate the clearing mechanism (270, 350) to clear the sealant dispensing pathway.

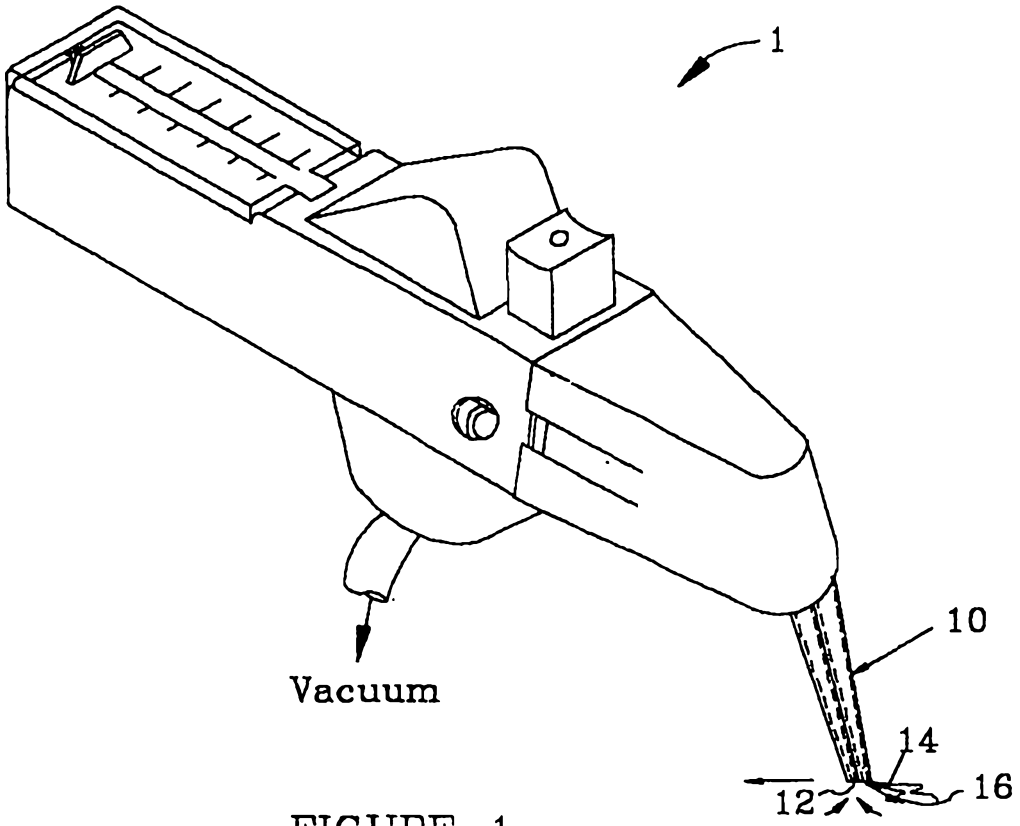

FIGURE 1

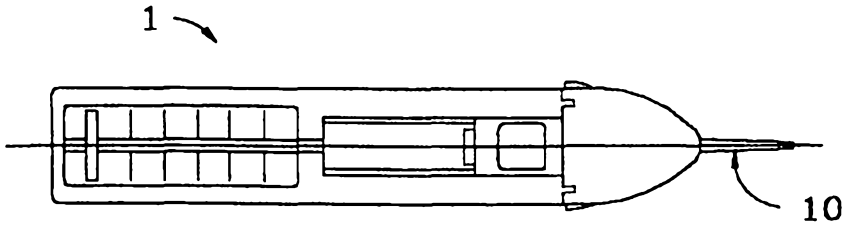

FIGURE 2A

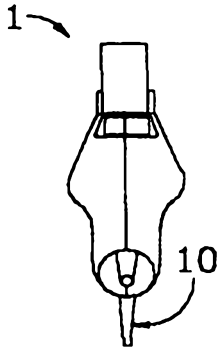

FIGURE 2C

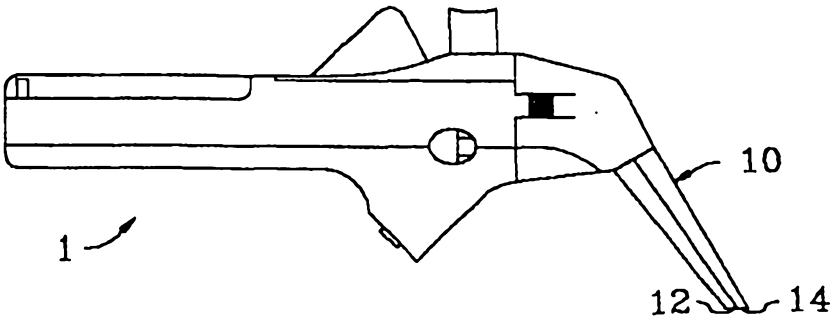

FIGURE 2B

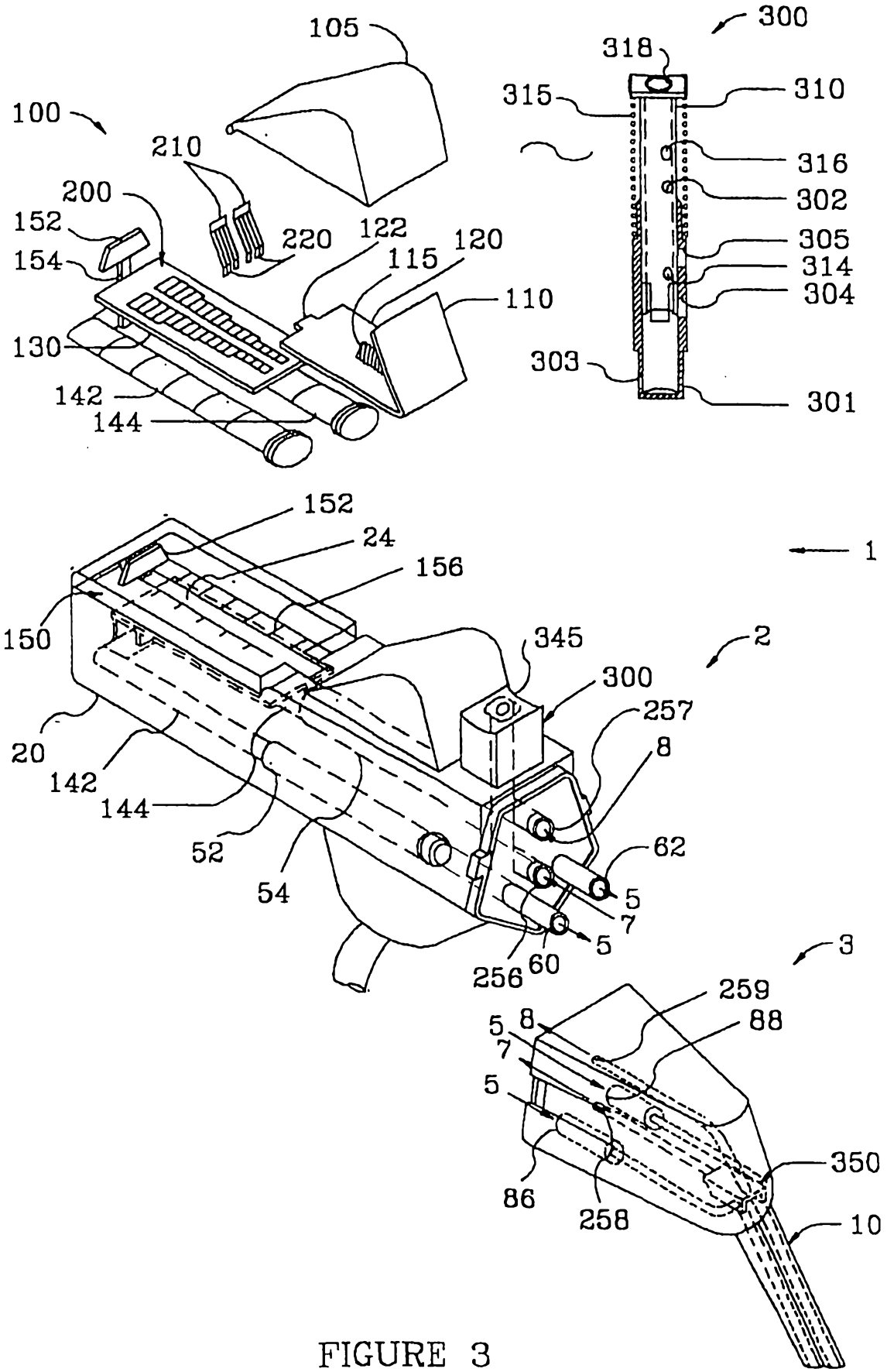
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FIGURE 3

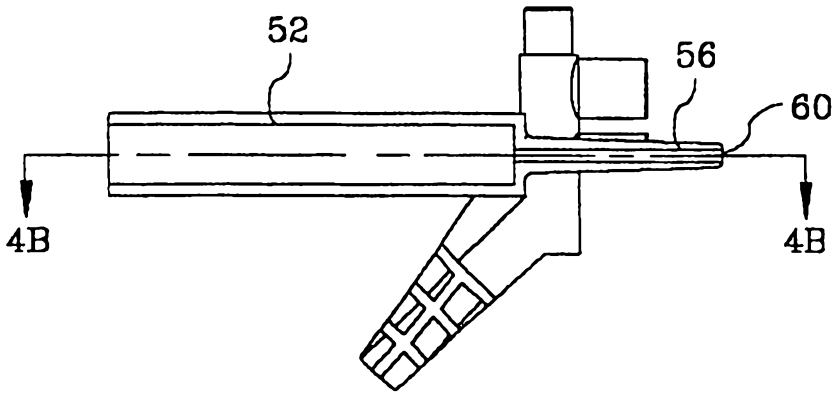

FIGURE 4A

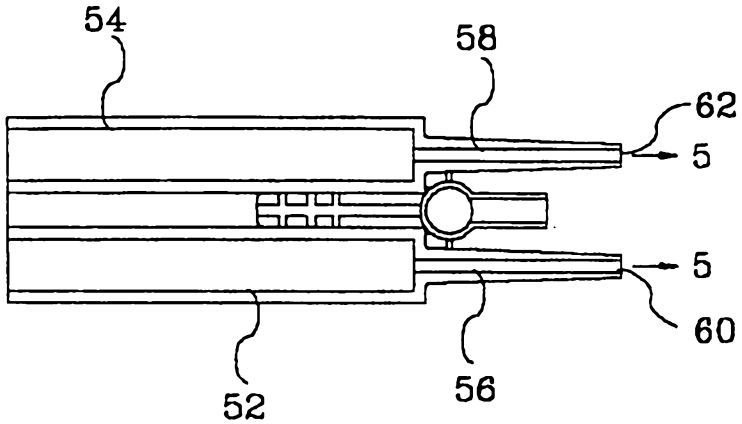

FIGURE 4B

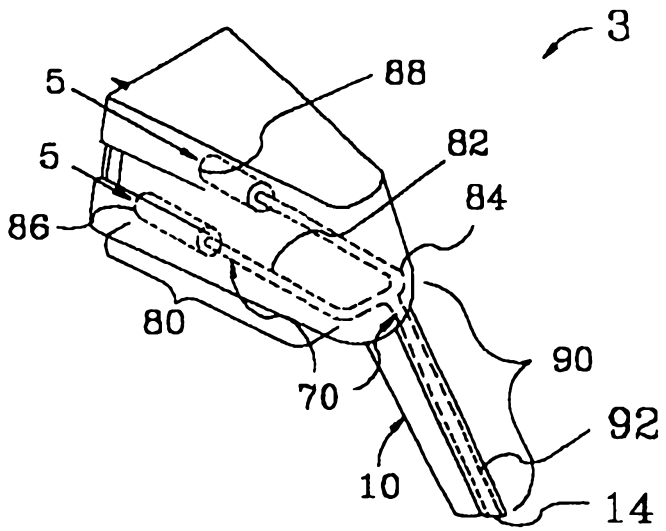

FIGURE 4C

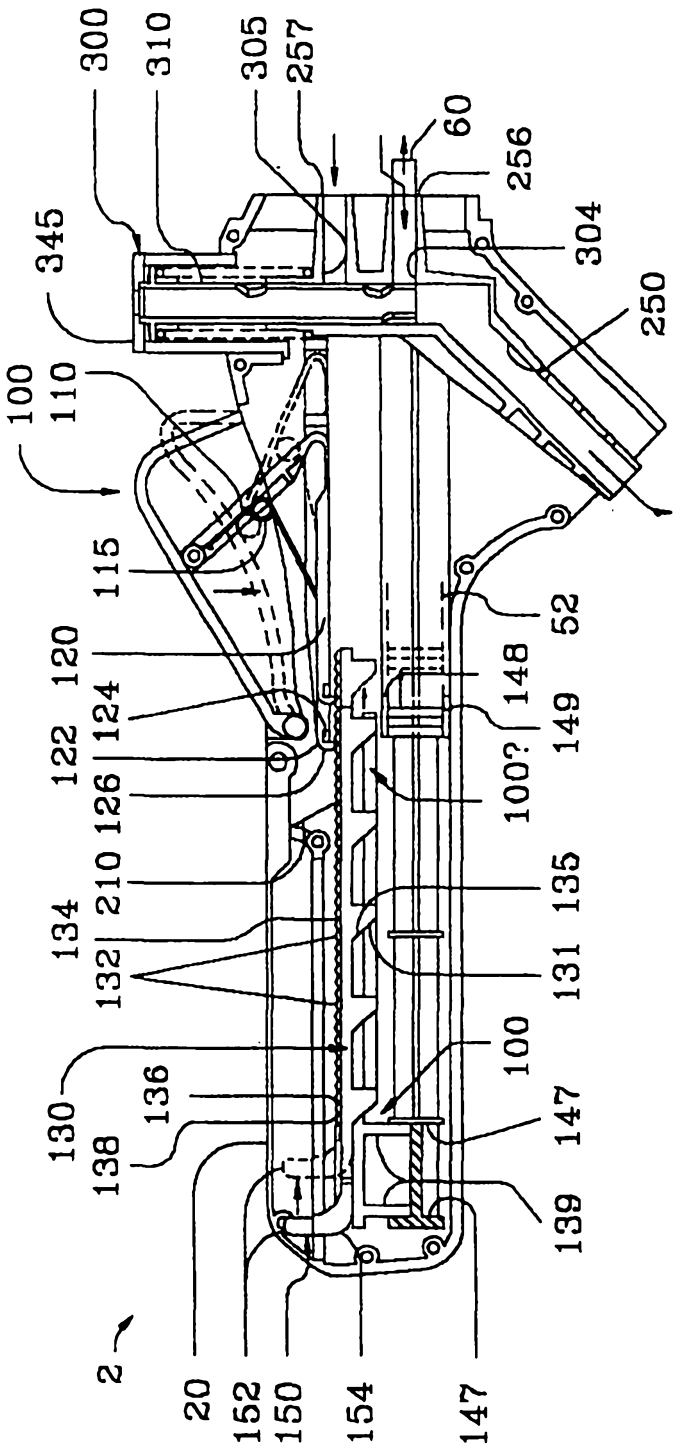

FIGURE 5

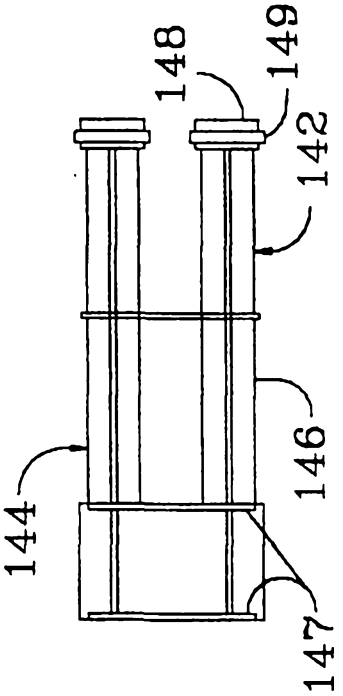

FIGURE 7

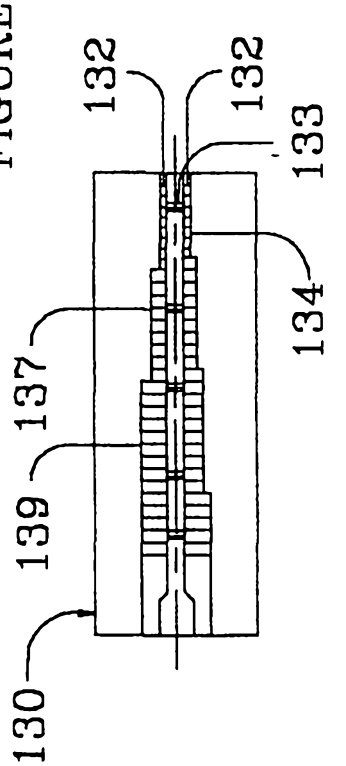

FIGURE 6

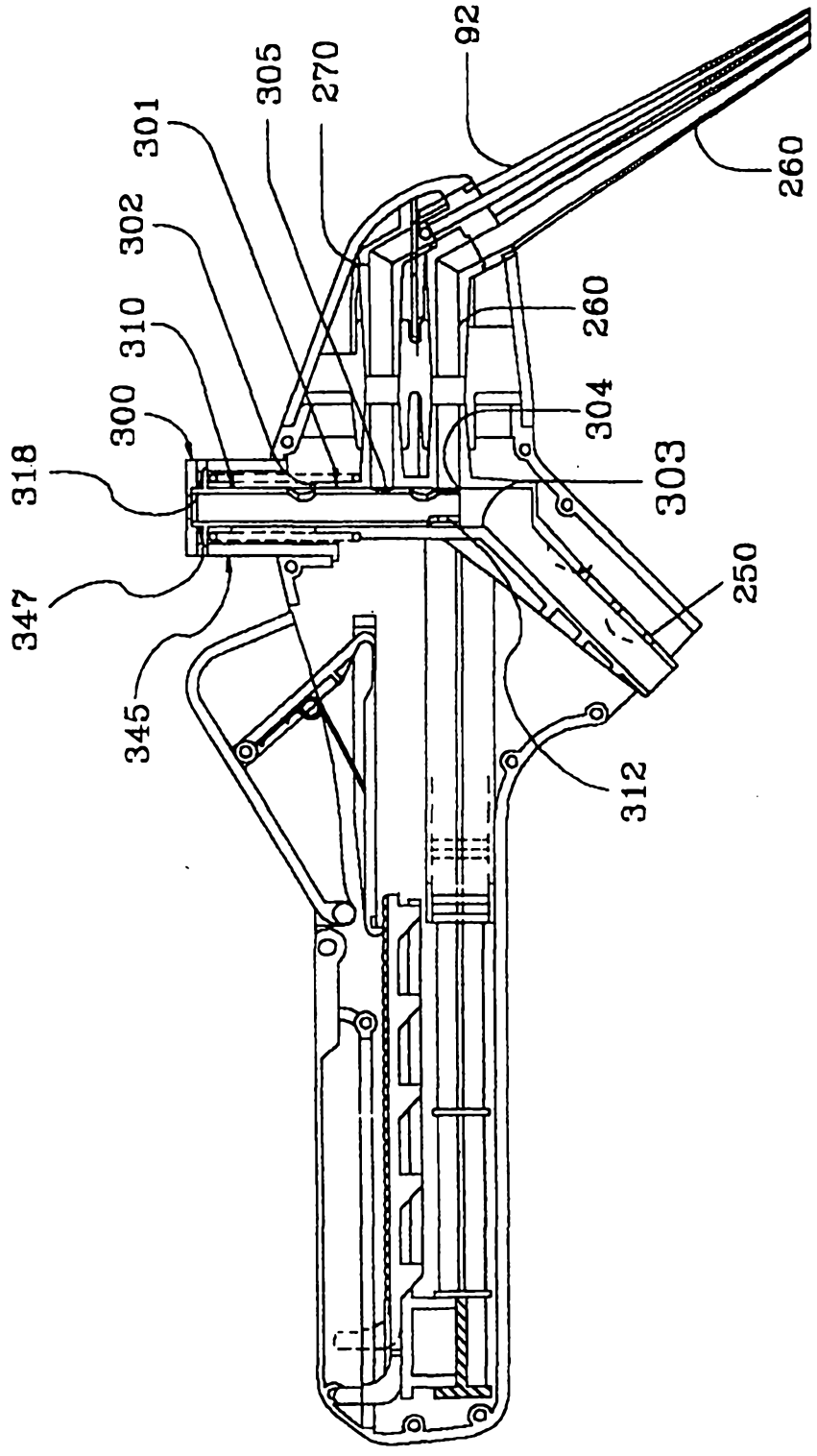

FIGURE 8

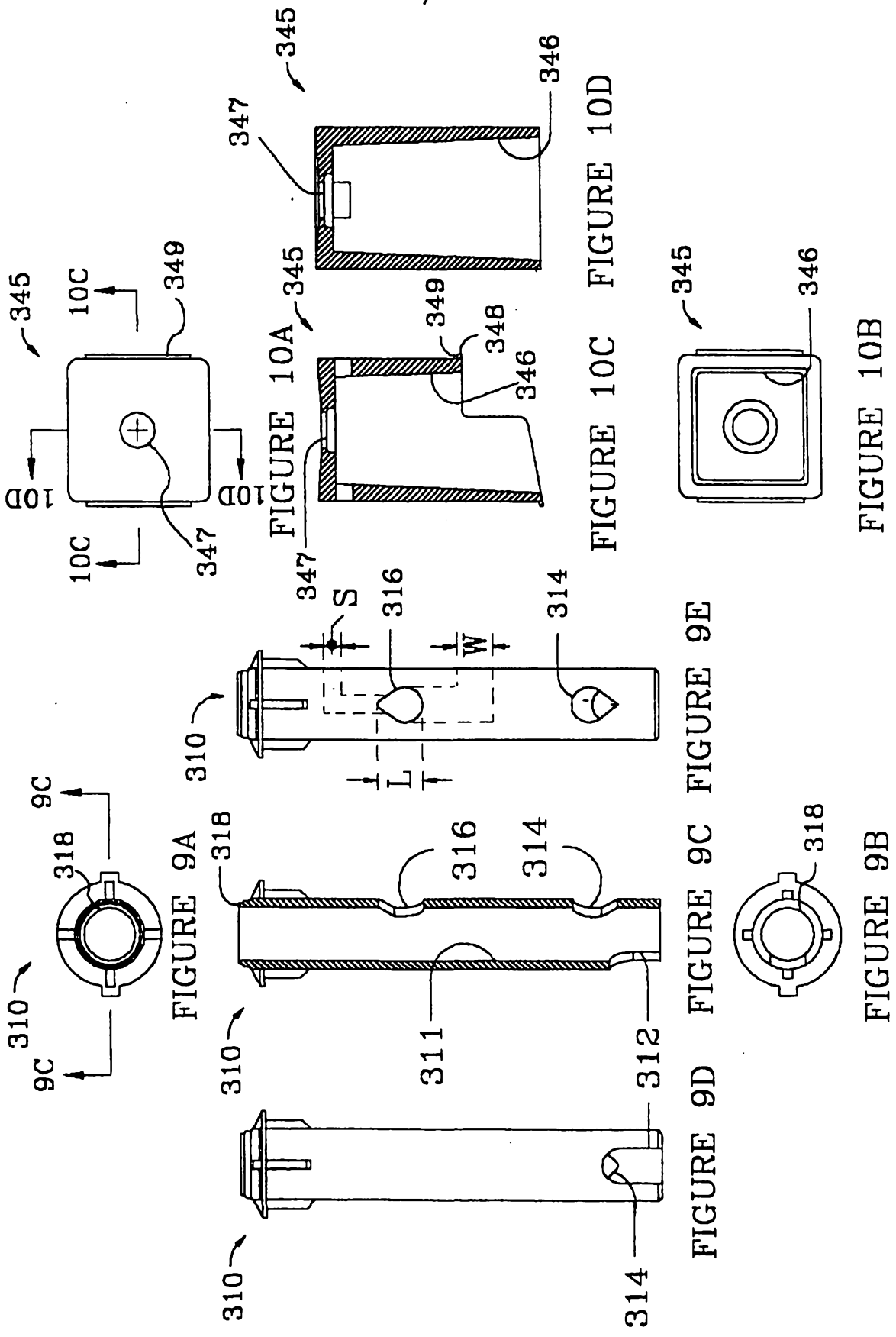
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FIGURE 10A
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FIGURE 10D
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FIGURE 10C
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FIGURE 10B
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FIGURE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

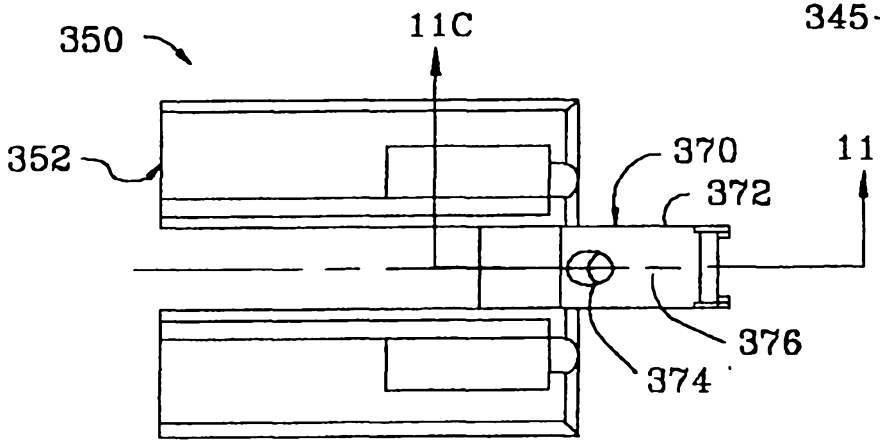

FIGURE 11A

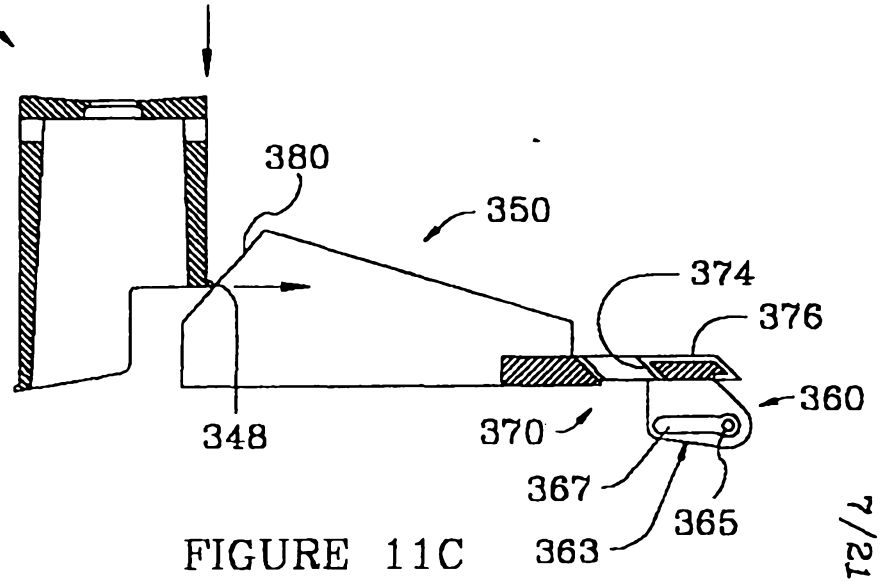

FIGURE 11C

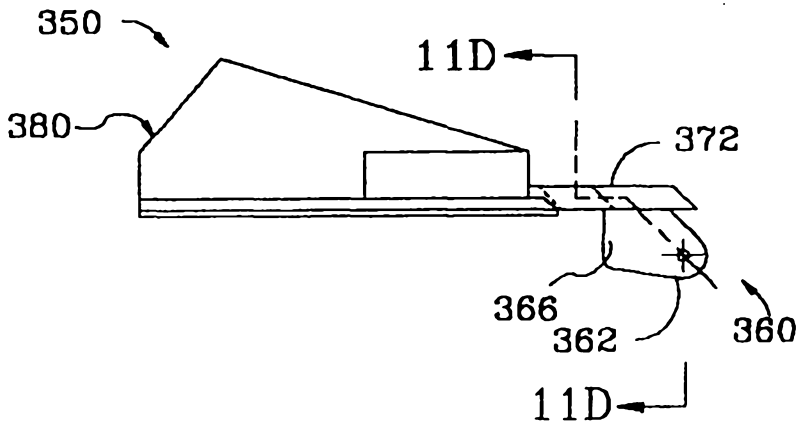

FIGURE 11B

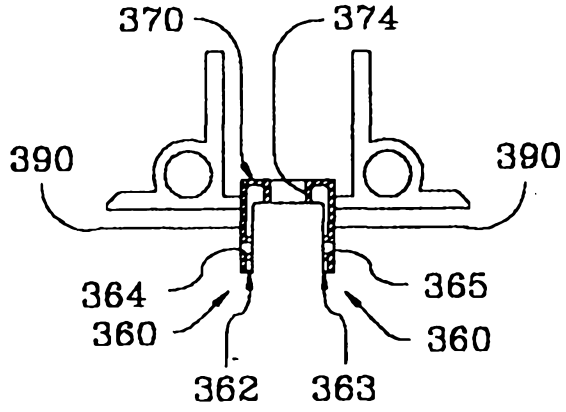

FIGURE 11D

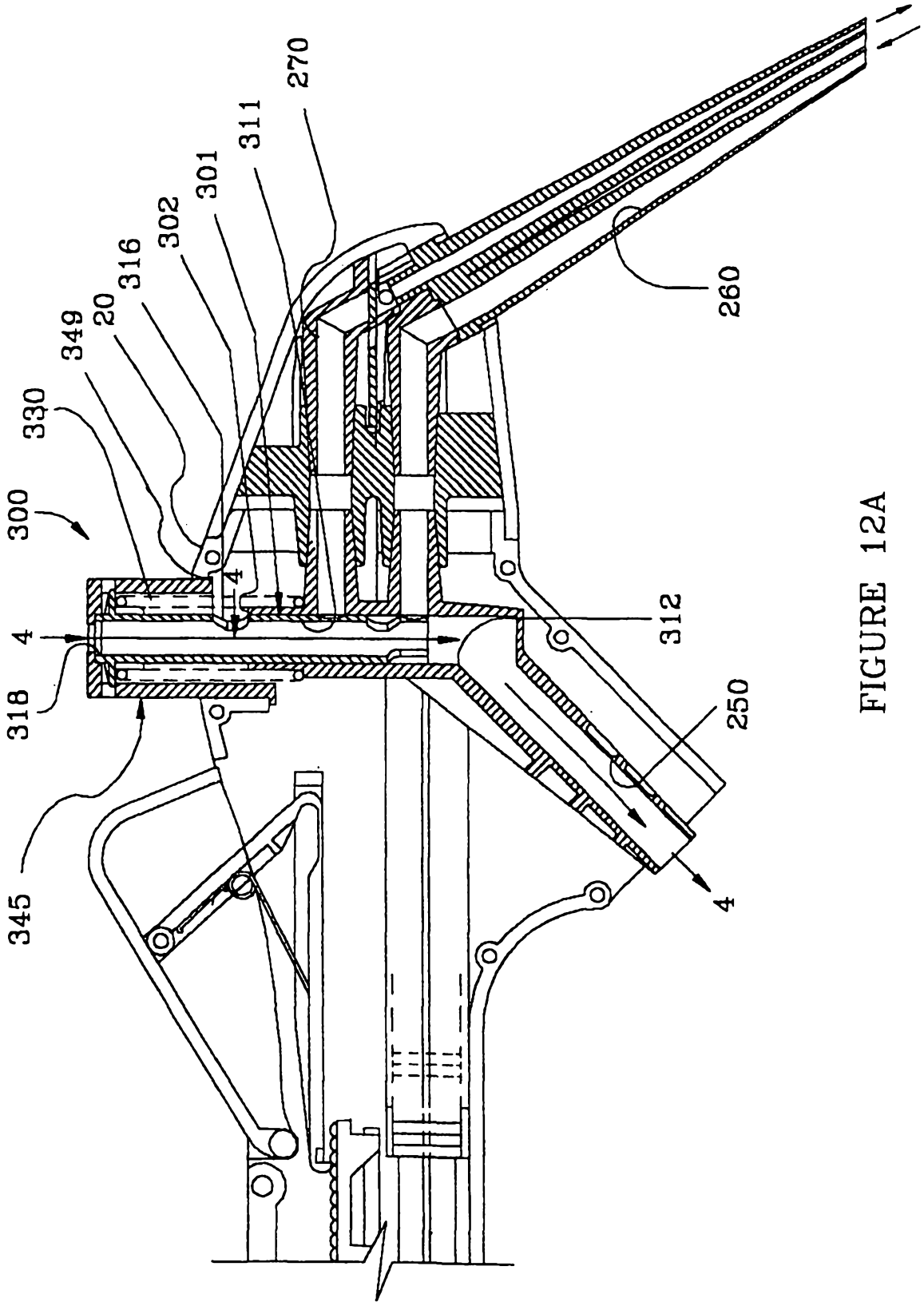

FIGURE 12A

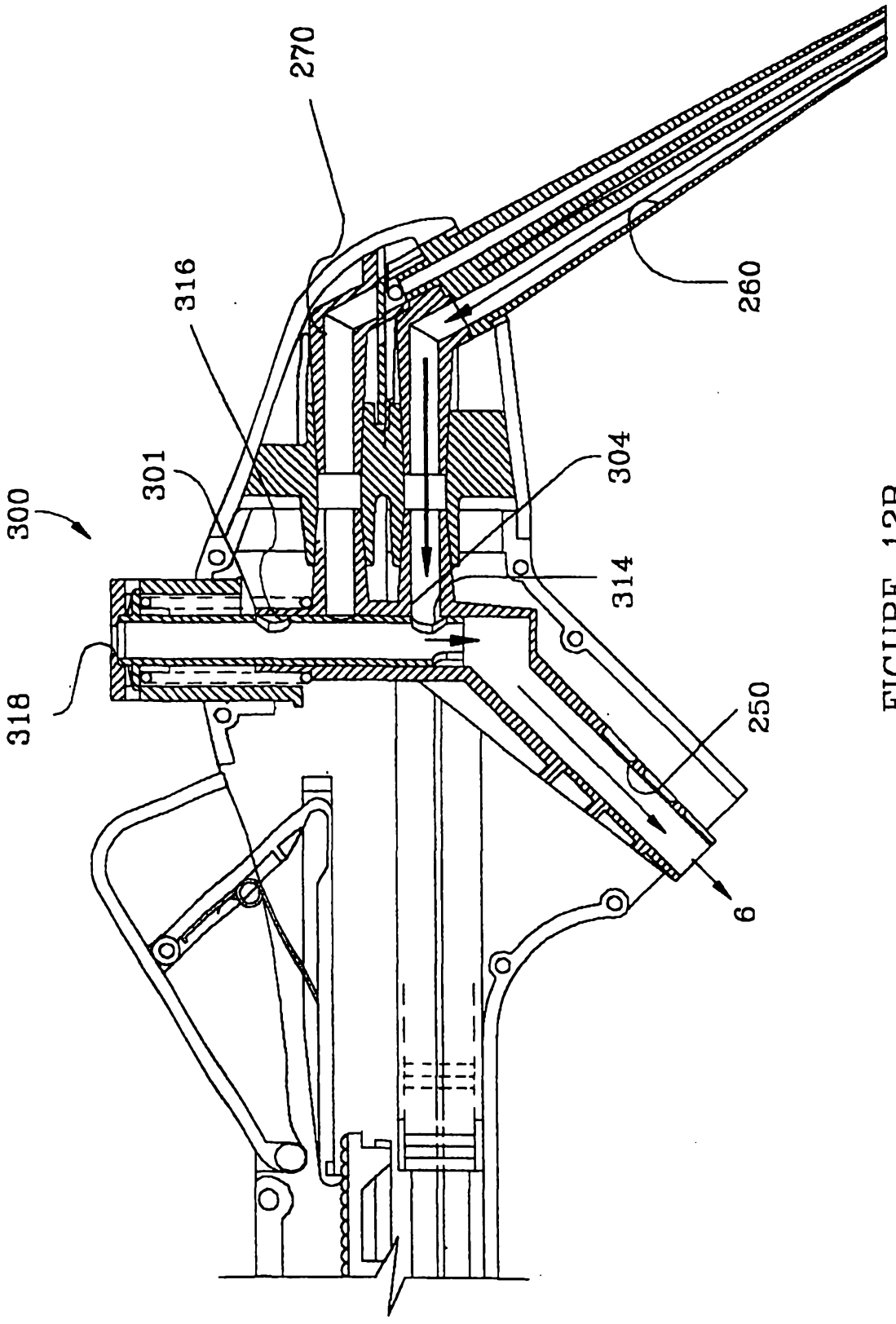

FIGURE 12B

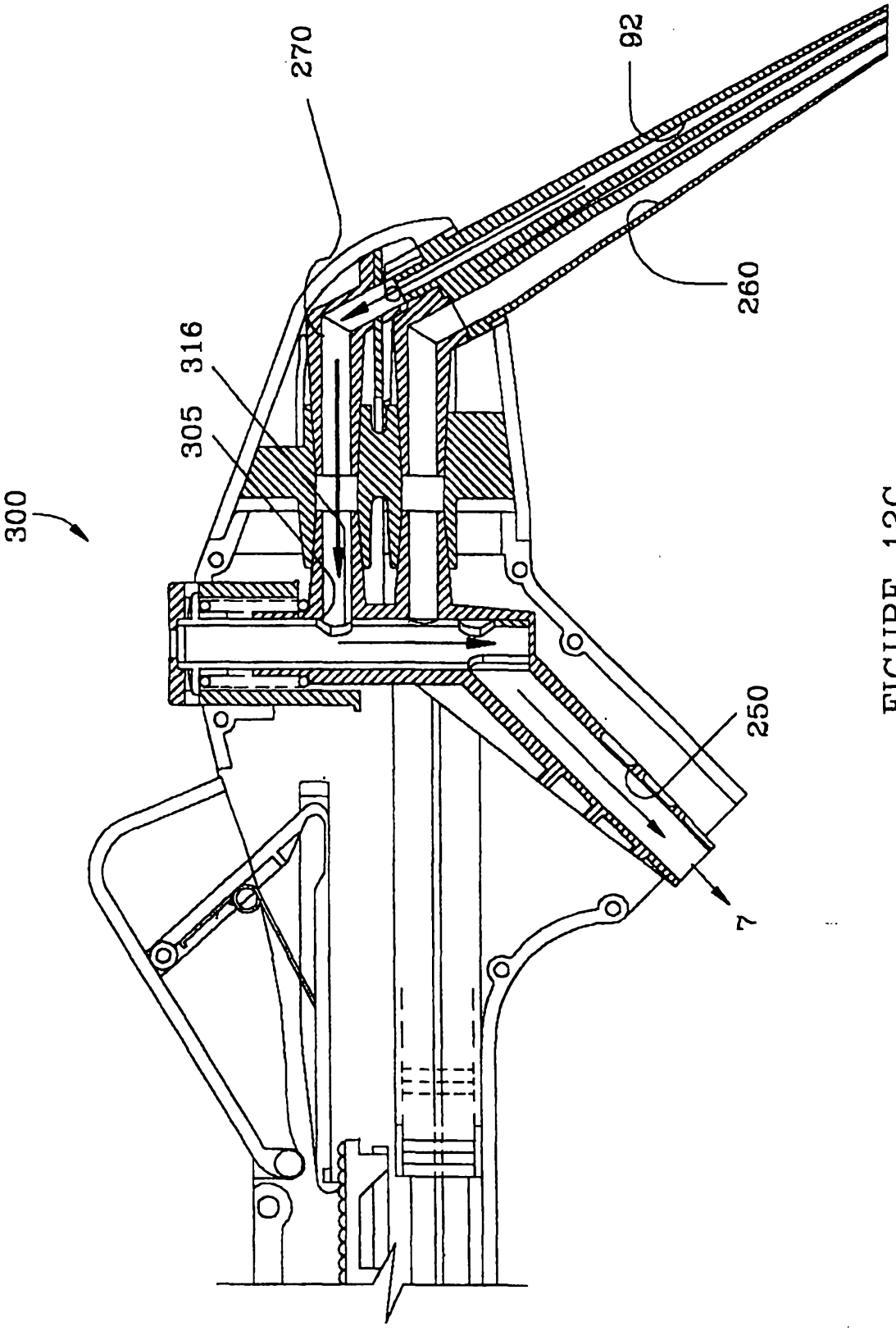

FIGURE 12C

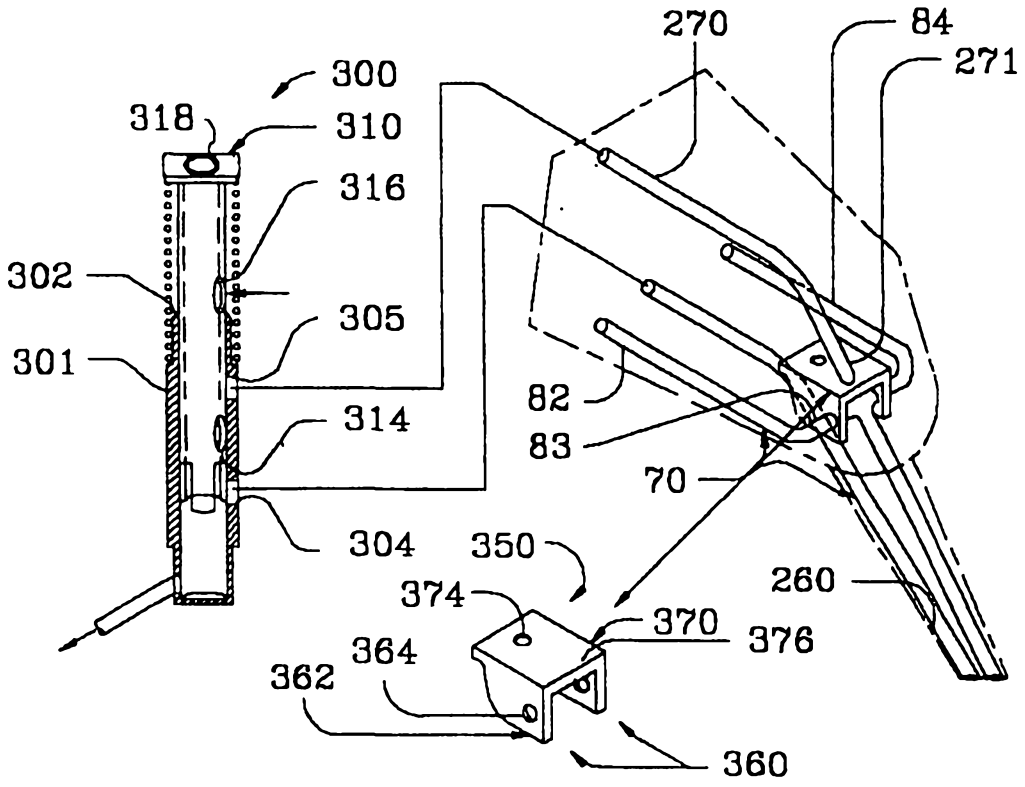

FIGURE 13A

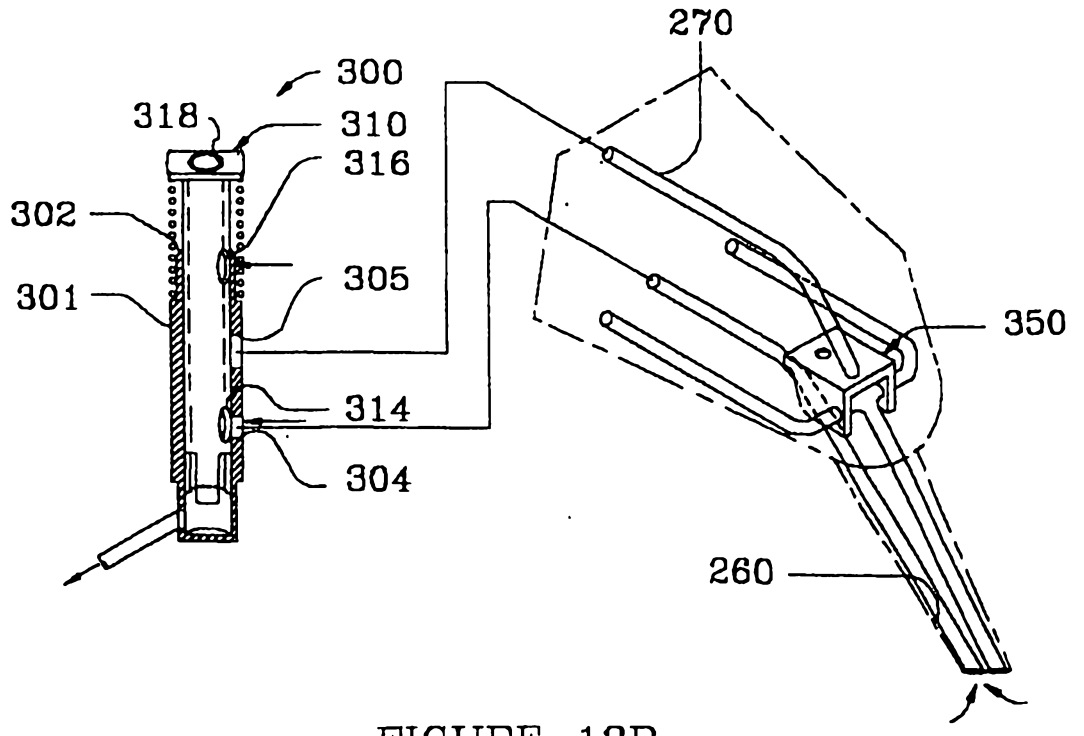

FIGURE 13B

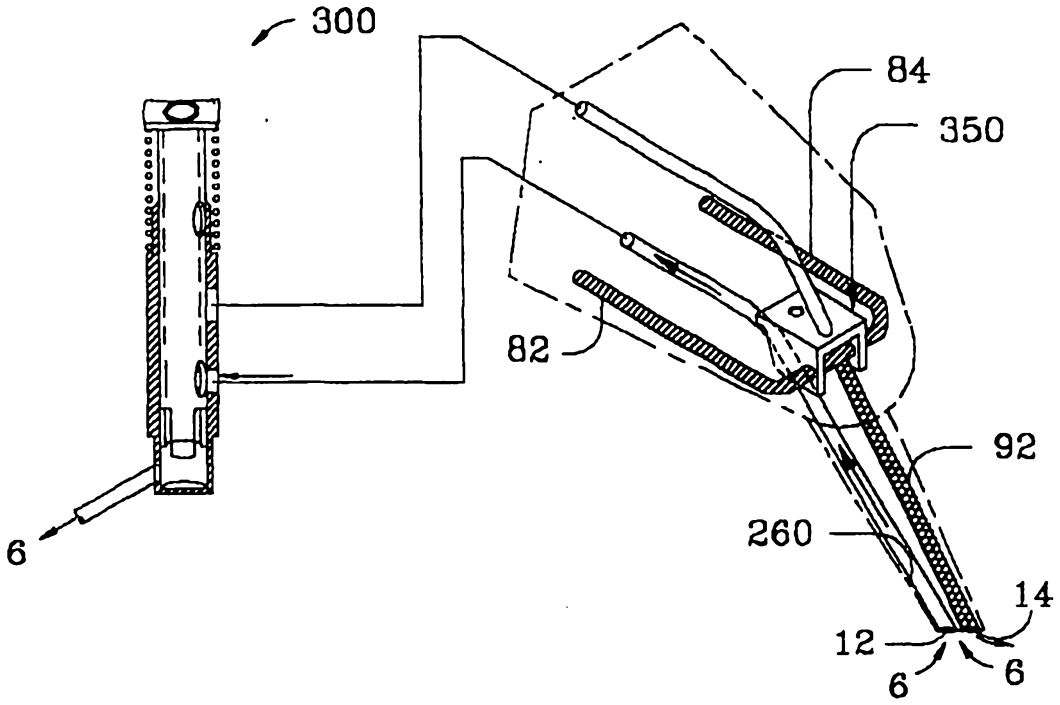

FIGURE 14A

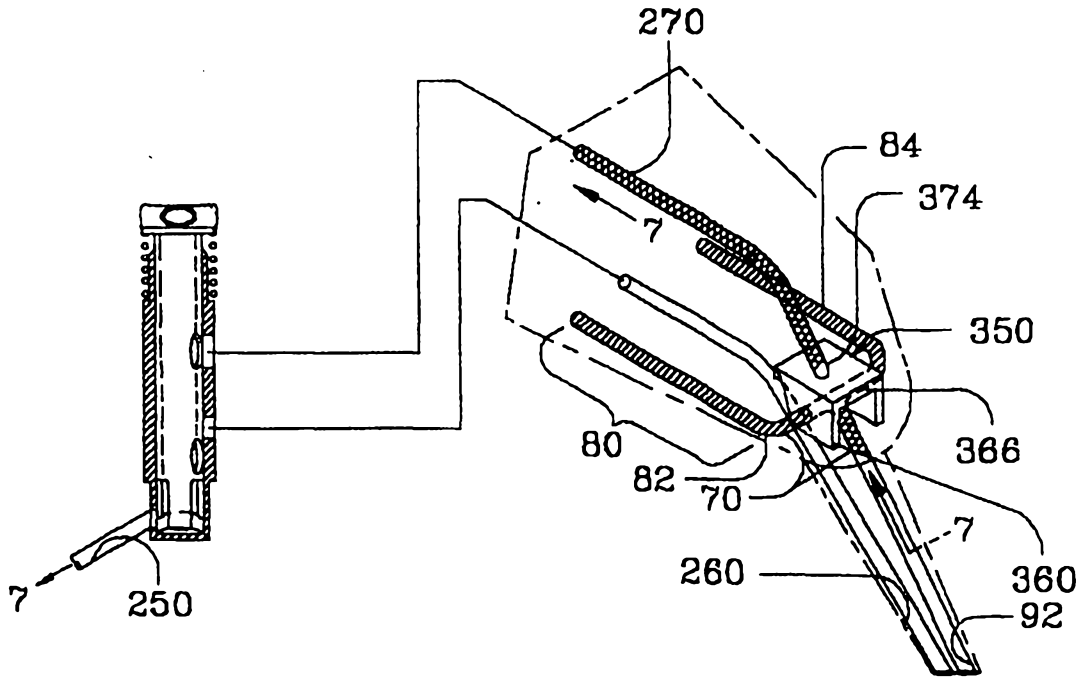

FIGURE 14B

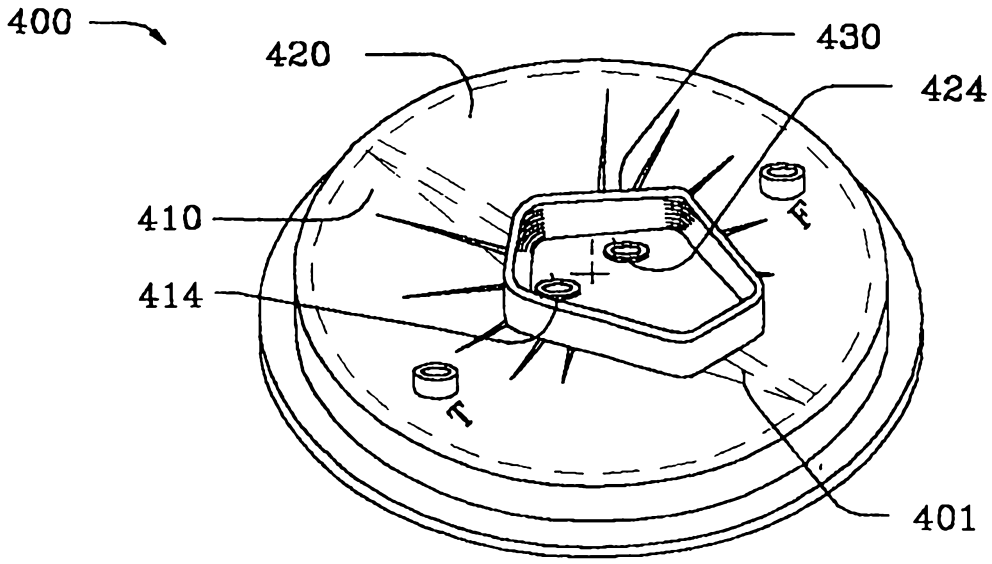

FIGURE 15

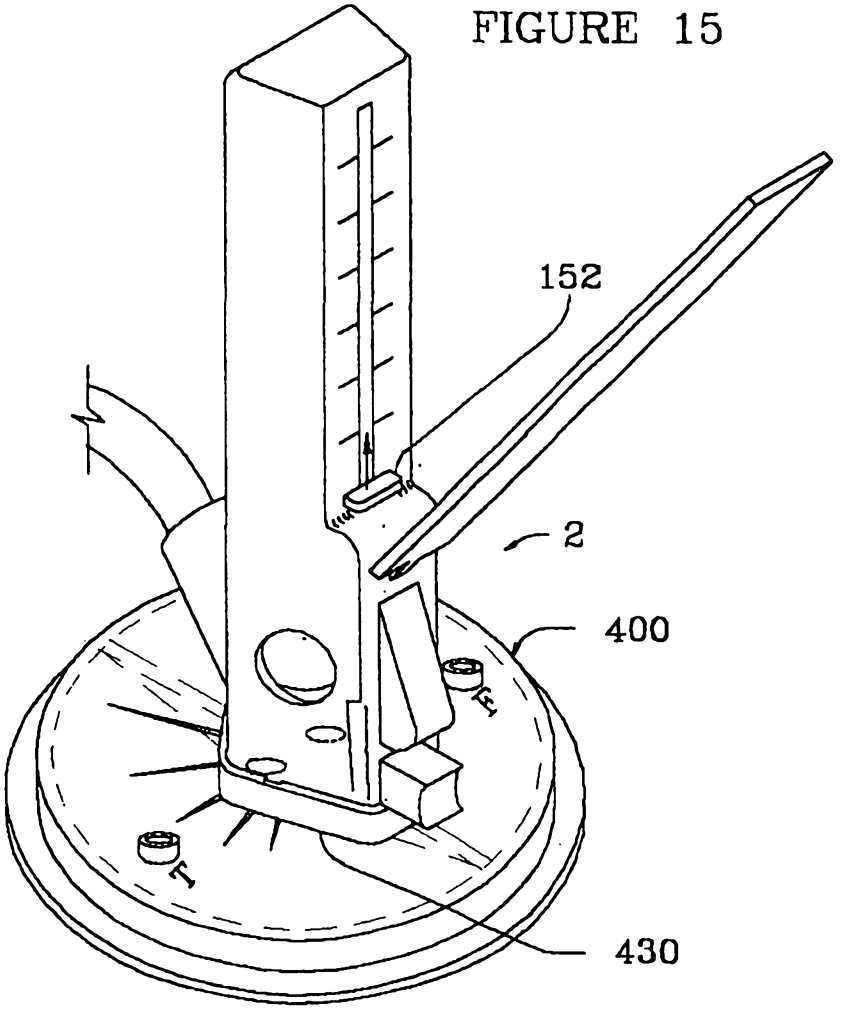

FIGURE 16

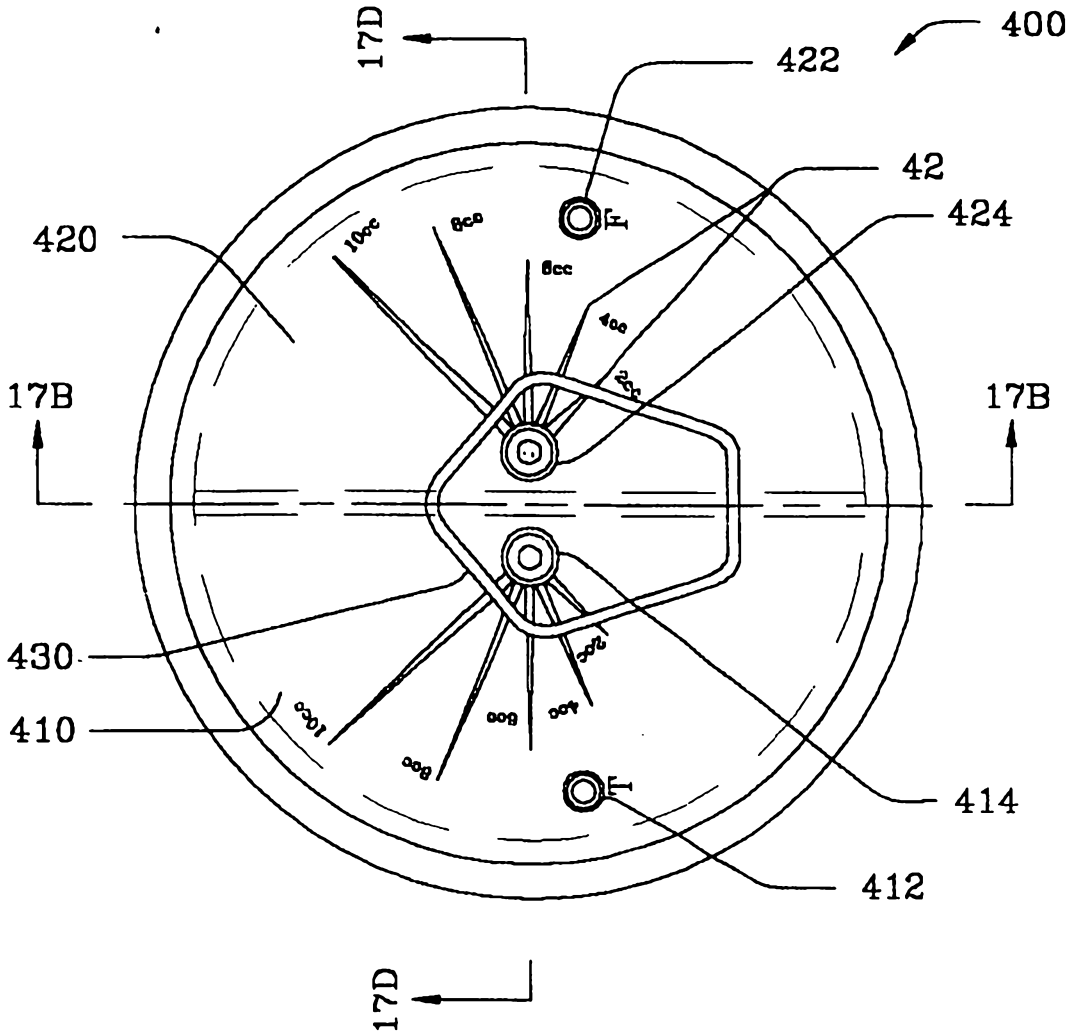

FIGURE 17A

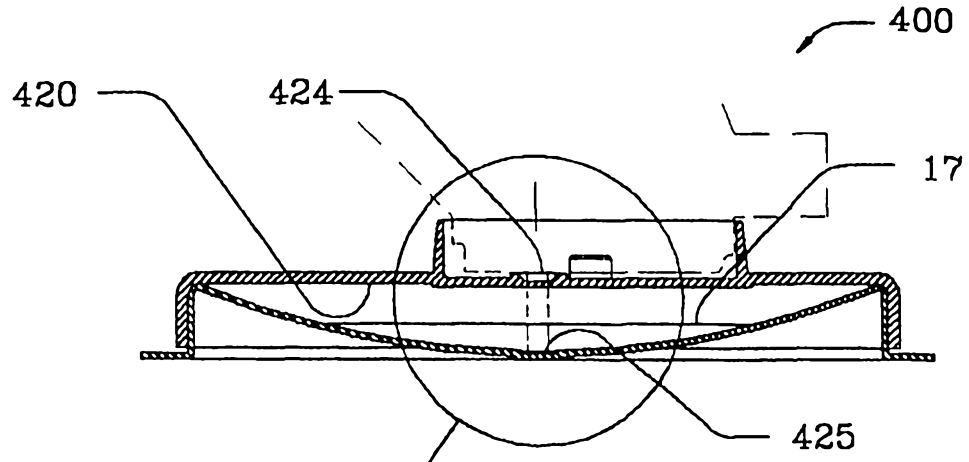

FIGURE 17B

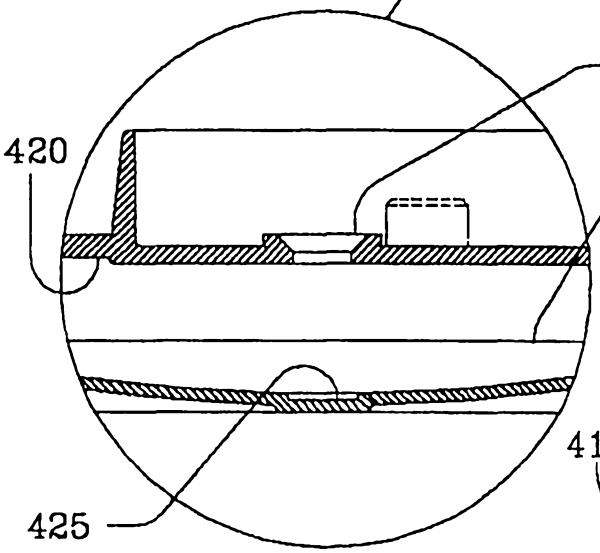

FIGURE 17C

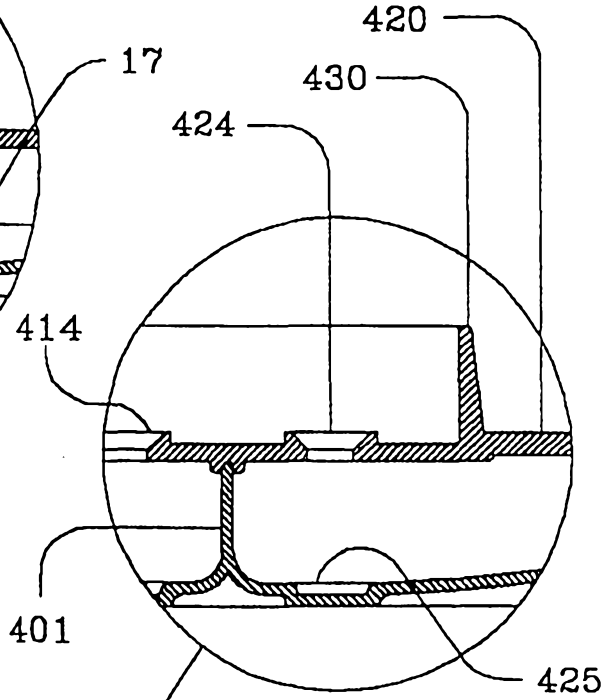

FIGURE 17E

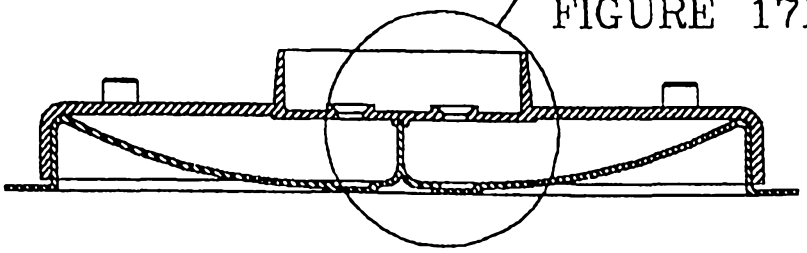

FIGURE 17D

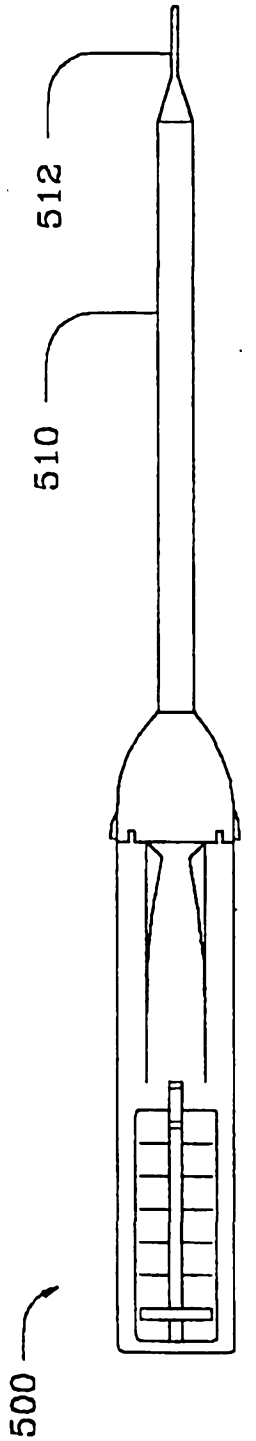

FIGURE 18B

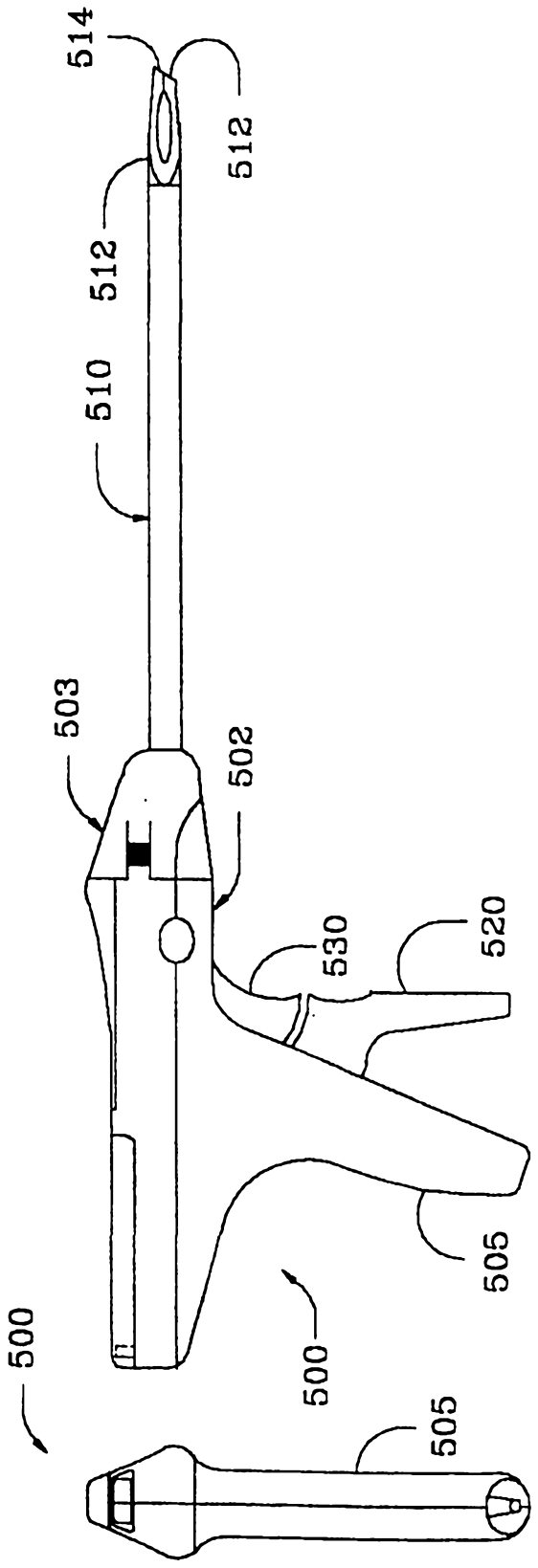

FIGURE 18A

FIGURE 18C

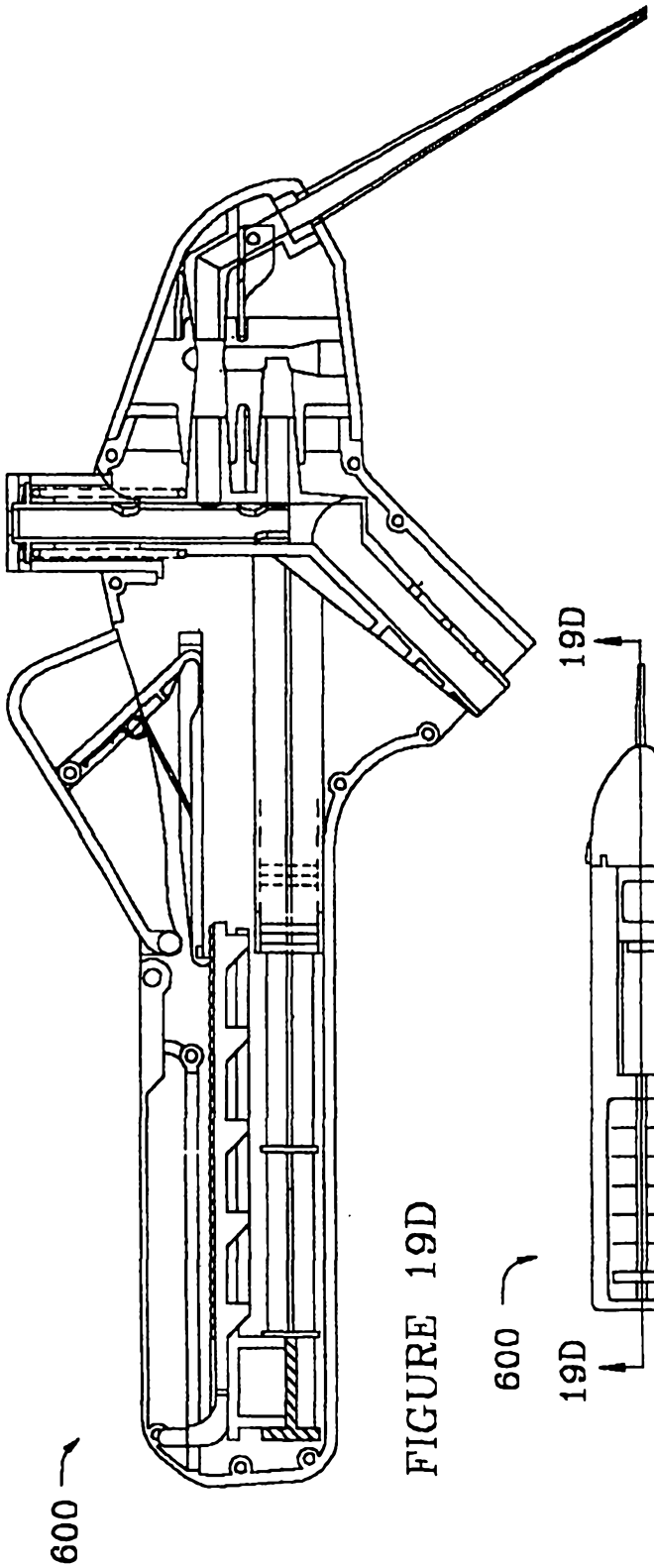

FIGURE 19D

FIGURE 19A

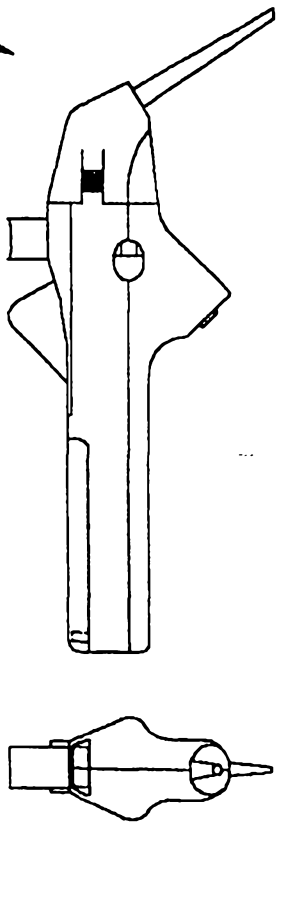

FIGURE 19B

FIGURE 19C

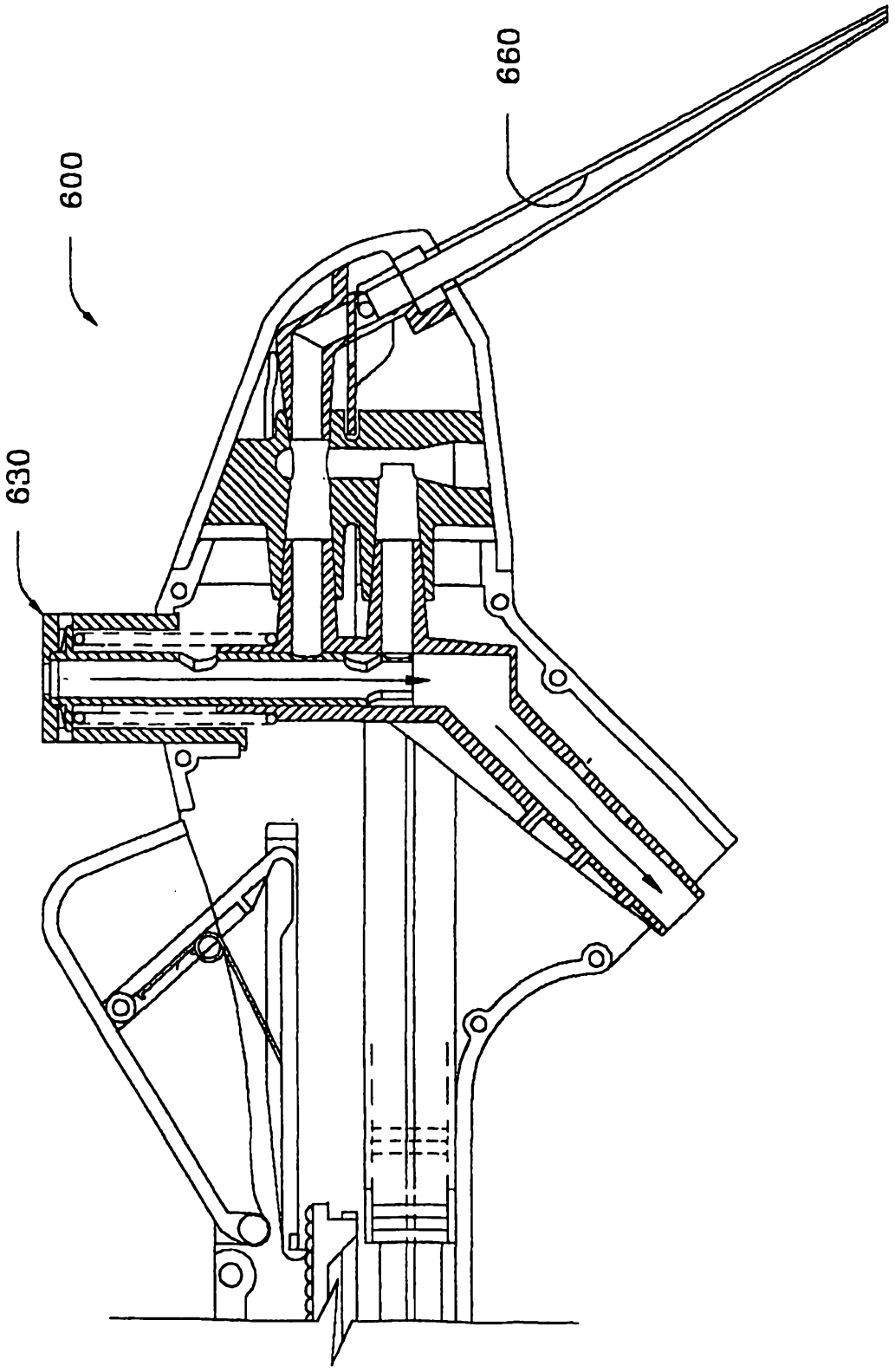

FIGURE 20A

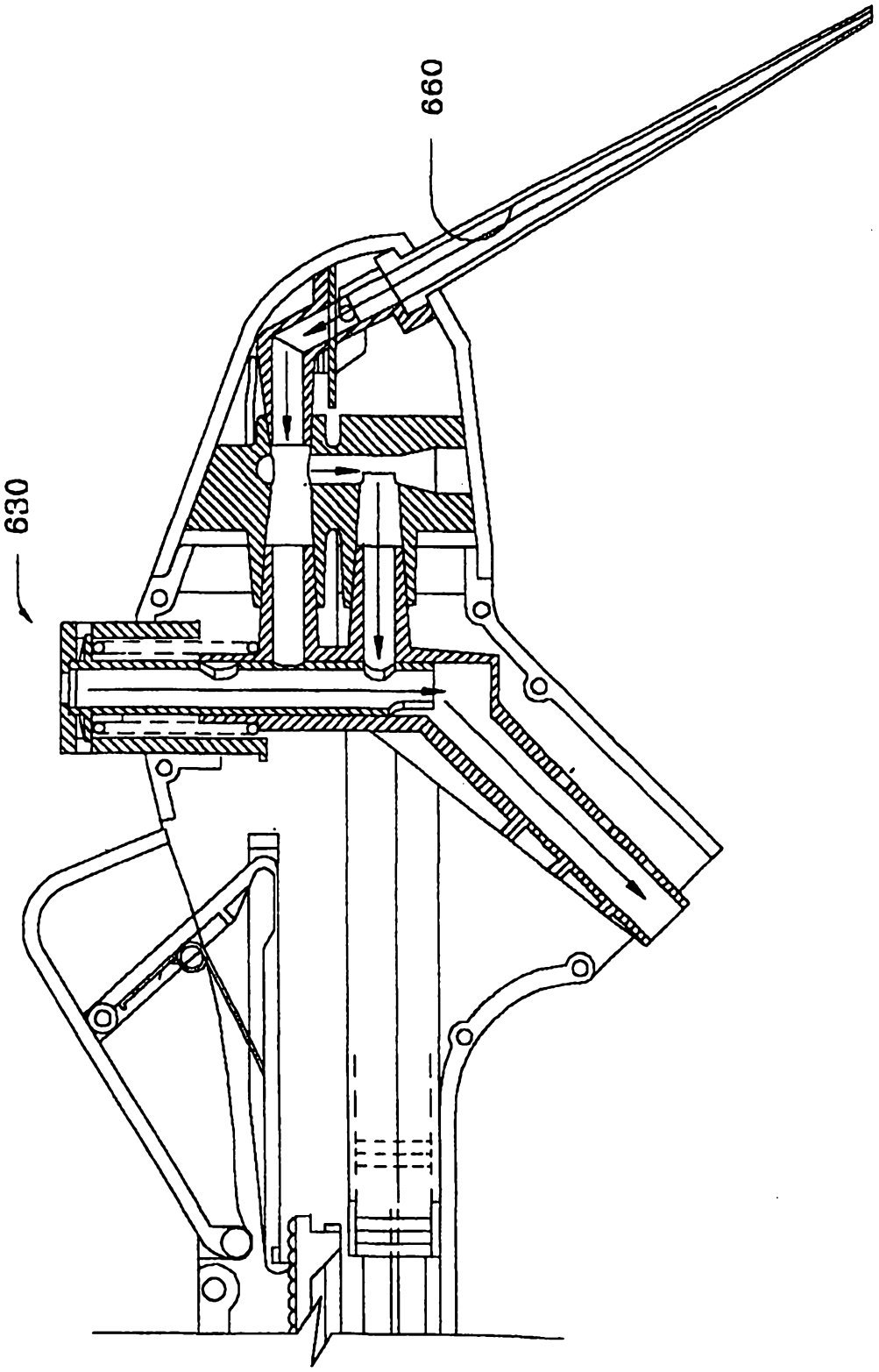

FIGURE 20B

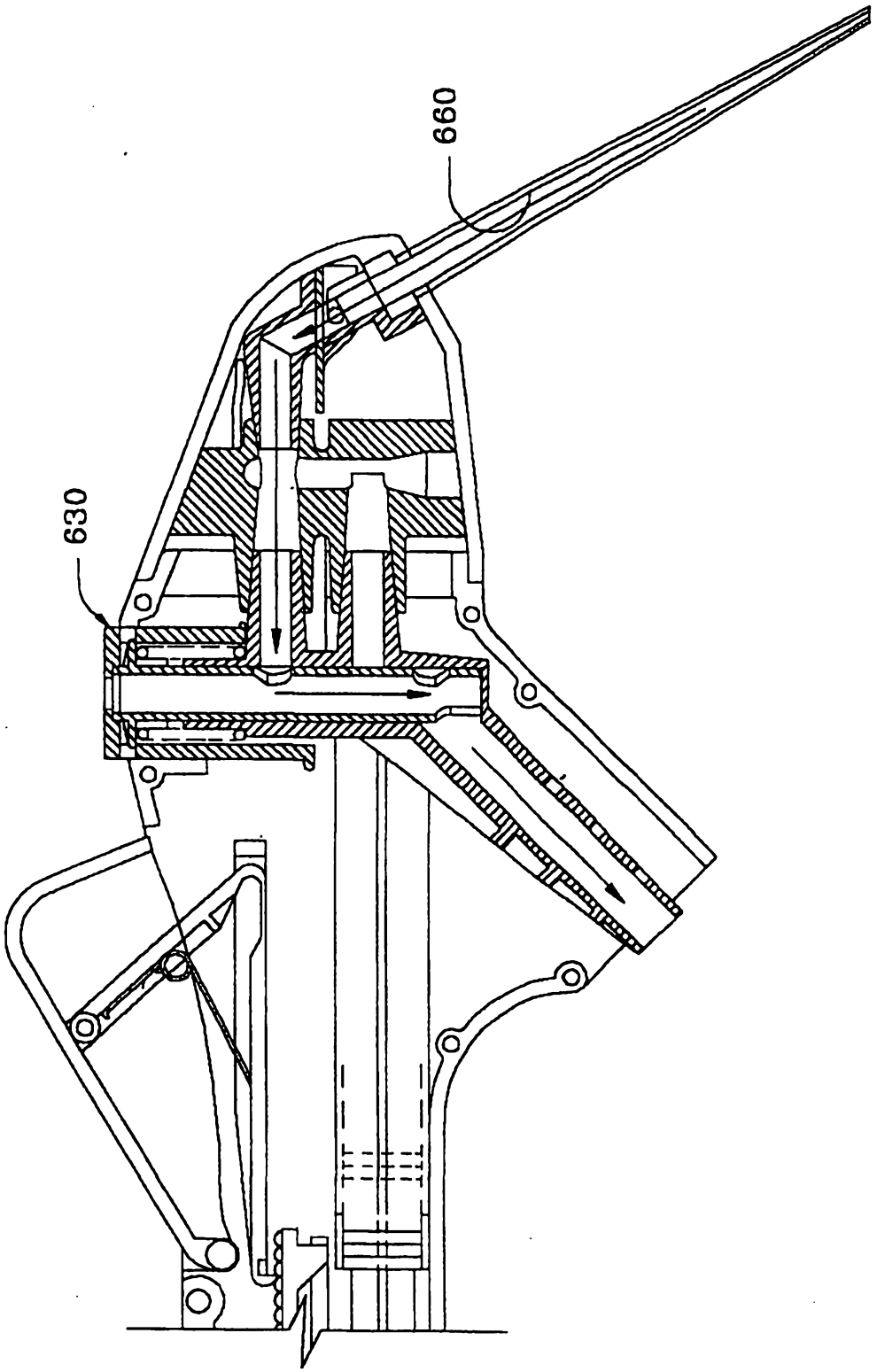

FIGURE 20C

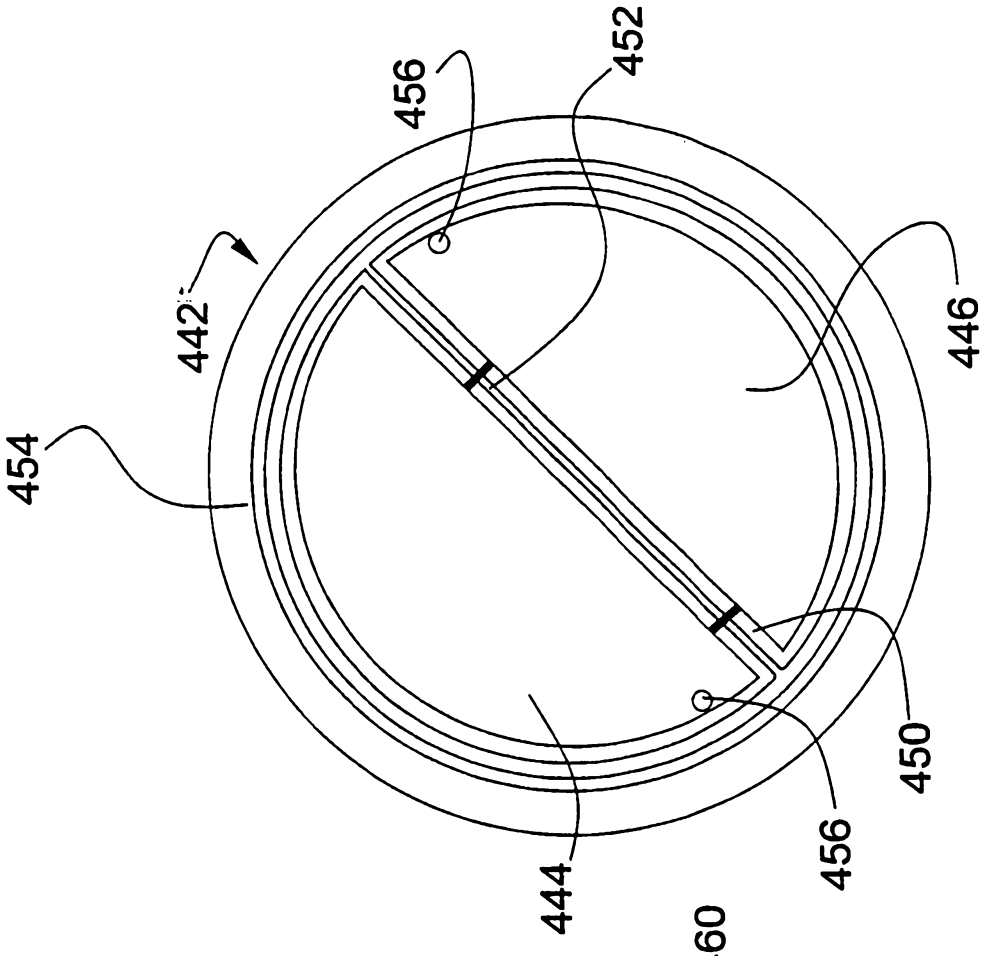

Figure 22

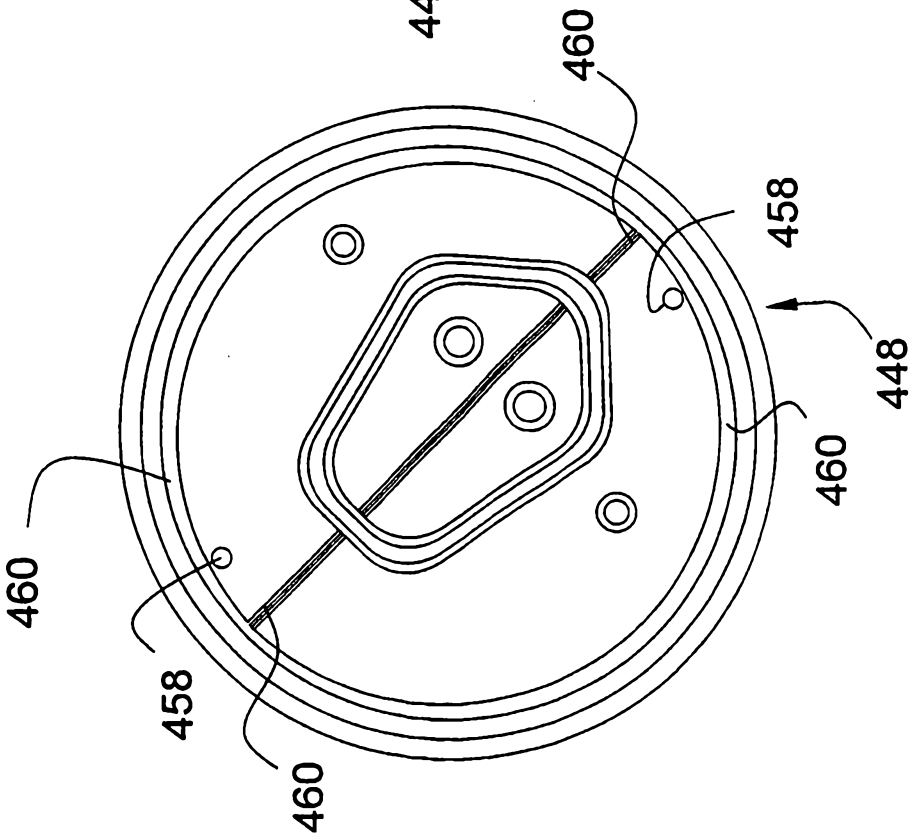

Figure 21