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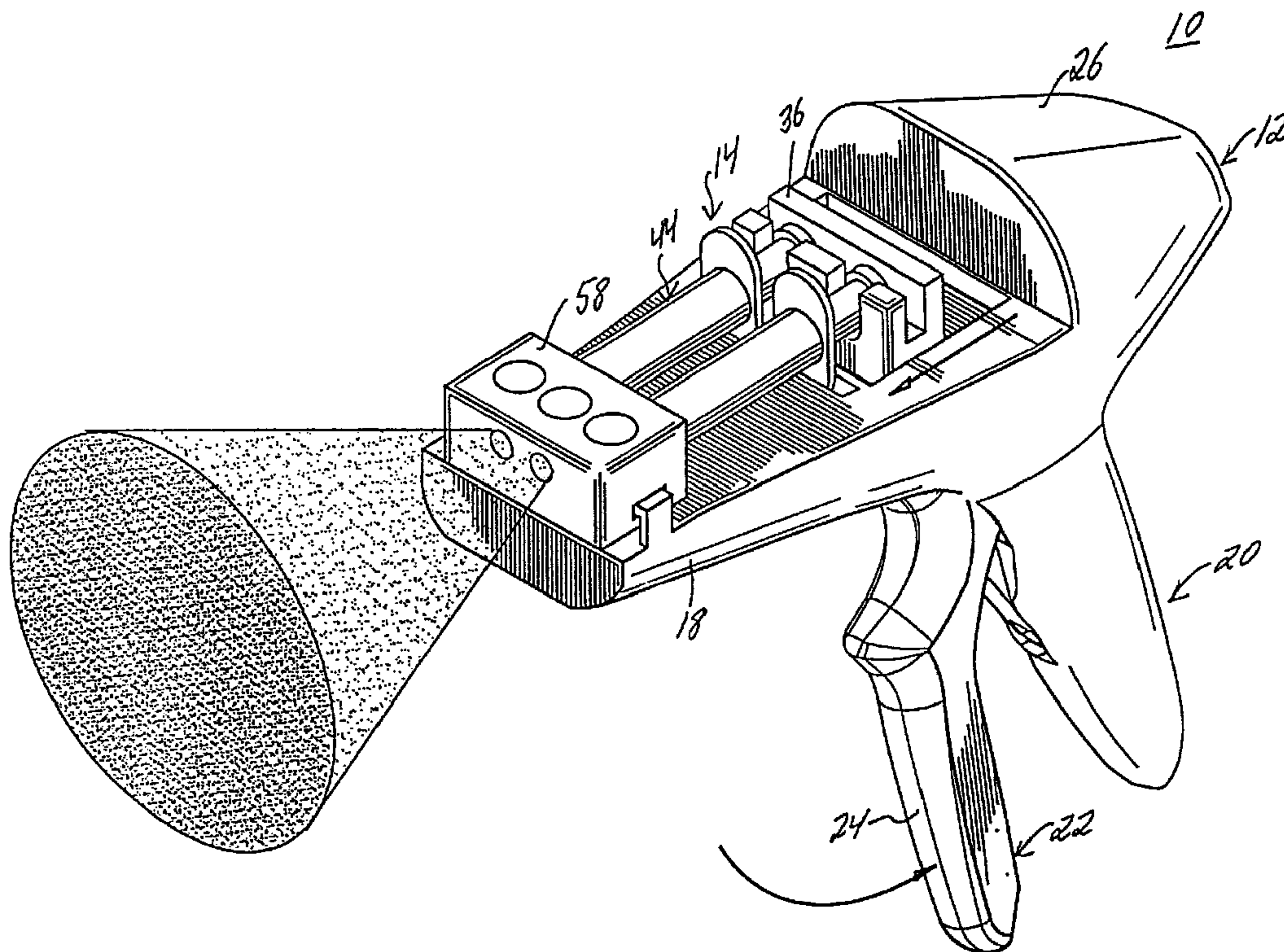
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(54) Titre : SYSTÈME D'APPLICATION DE COLLE DE FIBRINEUSE

(54) Title: FIBRIN GLUE APPLICATOR SYSTEM



(57) **Abrégé/Abstract:**

A fibrin glue applicator system is provided for dispensing a first and a second protein solution which form a biological adhesive when intermixed on an application site. The fibrin glue applicator system includes a coupler interface, a disposable loading unit (DLU), and a housing having a handle portion which includes a trigger operatively associated with a slide bar for dispensing the solutions from the DLU. Each piercer is in fluid communication with one of two cylinders of the DLU via a respective conduit connected to a respective main conduit. A first one-way valve is included within each conduit to open and close a path leading from the piercer to the main conduit. The first one-way valves are forced open by air pressure created when the loading lever connected to two pistons of the DLU is translated proximally causing the protein solutions to be transferred to their corresponding cylinder.

(57) **Abrégé(suite)/Abstract(continued):**

The DLU is then mounted to the housing. The solutions are dispensed via two dispensing orifices each in fluid communication with one of the main conduits. A second one-way valve is fixed within each main conduit in proximity to each dispensing orifice to open and close a path leading from each cylinder to its corresponding dispensing orifice. The second one-way valves open when the solutions are forcibly transferred from the cylinders to the main conduits by depressing the trigger for dispensing the solutions from the two dispensing orifices. The first and second protein solutions are preferably fibrinogen and thrombin solutions which intermix on the application site to form a fibrin sealant.

Attorney Docket: 203-2089ABSTRACT

A fibrin glue applicator system is provided for dispensing a first and a second protein solution which form a biological adhesive when intermixed on an application site. The fibrin glue applicator system includes a coupler interface, a disposable loading unit (DLU), and a housing having a handle portion which includes a trigger operatively associated with a slide bar for dispensing the solutions from the DLU. Each piercer is in fluid communication with one of two cylinders of the DLU via a respective conduit connected to a respective main conduit. A first one-way valve is included within each conduit to open and close a path leading from the piercer to the main conduit. The first one-way valves are forced open by air pressure created when the loading lever connected to two pistons of the DLU is translated proximally causing the protein solutions to be transferred to their corresponding cylinder. The DLU is then mounted to the housing. The solutions are dispensed via two dispensing orifices each in fluid communication with one of the main conduits. A second one-way valve is fixed within each main conduit in proximity to each dispensing orifice to open and close a path leading from each cylinder to its corresponding dispensing orifice. The second one-way valves open when the solutions are forcibly transferred from the cylinders to the main conduits by depressing the trigger for dispensing the solutions from the two dispensing orifices. The first and second protein solutions are preferably fibrinogen and thrombin solutions which intermix on the application site to form a fibrin sealant.

FIBRIN GLUE APPLICATOR SYSTEMBACKGROUND1. Technical Field

5 The disclosure relates generally to a fibrin glue applicator system for dispensing a first and a second component of a tissue sealant based on human or animal proteins and, more particularly, to an applicator system for dispensing a first and a second protein solution to be applied to tissues or organs to form a fibrin sealant for sealing wounds, stopping bleeding and the like.

10 2. Description of Related Art

A fibrin sealant is a biological adhesive formed by mixing two protein components, namely, fibrinogen and thrombin. Each protein component is derived from human plasma and is subjected to virus elimination procedures.

15 The components are typically individually dehydrated and stored in separate vials as sterile freeze-dried powders.

It is known that purified fibrinogen and thrombin, together with a variety of known adjuvants, can be combined in vitro to produce a polymer having great potential

20 benefit, both as a hemostatic agent and as a tissue adhesive. Because of the rapid polymerization upon intimate interaction of fibrinogen and thrombin, it is important to maintain these two blood proteins separate until applied at the application site. These protein solutions are generally

mixed and dispensed by devices such as a dual syringe apparatus.

One dual syringe apparatus for applying a fibrinogen-based tissue adhesive is disclosed in U.S. Pat. No. 4,359,049 to Redl et al. This reference discloses a mechanism in which two standardized one-way syringes are held in a support having a common actuating means. The dispensing end of each syringe is inserted into a collection manifold where the two components are mixed. The components are then dispensed through a common needle capable of covering a limited area of the application site.

Typical devices for mixing and dispensing solutions of fibrinogen and thrombin require the addition of these proteins in powdered form to the body of the syringe. This makes the proteins susceptible to contamination by impurities which may enter the syringe body. Further still, the use of the syringe body to mix the proteins with water to create the protein solutions can cause the solutions to leak out from either the dispensing end of each syringe or the proximal end of the syringe body.

A dual syringe apparatus for the application of fibrinogen and thrombin solutions to an application site generally contains several parts, such as a syringe plunger, a "Y" manifold connector, a dispensing needle, a syringe holder, syringe needles, and conduits for transporting the solutions to the dispensing needle. Therefore, fibrin sealant applicators, such as disclosed in U.S. Patent No. 4,359,049 to Redl et al discussed above, and in U.S. Patent Nos. 4,874,368 to Miller et al and 4,979,942 to Wolf et al are difficult to reuse. The replenishment of the protein components typically requires

removing a clip which couples the syringe plunger,
removing the syringe plunger, detaching the syringes from
the "Y" connector, removing the syringes from the holder,
inserting new syringes, affixing the syringes to the "Y"
5 connector, adding fibrinogen to one syringe and thrombin
to another syringe, adding sterile water to each syringe,
replacing the syringe plunger, replacing the plunger clip,
and mixing the solutions. In an application where time
may be of the essence, such a lengthy replenishing process
10 is impractical and cumbersome.

SUMMARY

In accordance with an embodiment of the present
invention there is provided an applicator system for
dispensing from respective dispensing orifices at least
15 two components for forming a multicomponent biological
adhesive, the applicator system comprising: a housing
configured to receive a loading unit having at least two
piston assemblies, each of the at least two piston
assemblies having a piston matingly engaging the proximal
20 end of a cylinder configured for retaining one of the at
least two components, and for dispensing the one component
through a distal end of the cylinder; and an activator
assembly provided on the housing having an activator
movable from a first position to a second position to
25 compress each of the at least two pistons to dispense the
at least two components through the at least two conduits
in the dispensing unit; and characterized by: a dispensing
unit having at least two conduits which in use are in
fluid communication with the respective distal ends of the
30 cylinder of the at least two piston assemblies and with
respective ones of the dispensing orifices, the dispensing
unit including a coupler interface having at least two
piercers.

In accordance with another embodiment of the present invention there is provided a manually-operated applicator for dispensing a first and second component of a biological adhesive, the applicator comprising: a
5 conduit assembly having a first pair of conduits and a first valve movable from a closed position to an open position; a piston assembly having a first cylinder containing the first component and a second cylinder containing the second component, the first cylinder being
10 in communication with a first of the first pair of conduits and the second cylinder being in communication with a second of the first pair of conduits; an activator assembly having an activator for imparting distal pressure to the first and second cylinders to effect dispensing of
15 the first and second components to the first pair of conduits and move the first valve from the closed position to the open position; and a coupler interface in engagement with the conduit assembly and configured to receive, in use, at least two vials storing the first and
20 second components for replenishing the first and second cylinders.

Yet another embodiment of the present invention provides a kit for dispensing from respective vials a first and second component of a biological adhesive, the
25 kit comprising: a loading unit having at least two piston assemblies, each of the at least two piston assemblies having a piston matingly engaging a cylinder configured for retaining one of the first and second components; a housing configured to receive the loading unit; a
30 dispensing unit having at least two conduits in fluid communication with the cylinders; a coupler interface configured for receiving the respective vials storing the first and second components therein, the coupler interface

having at least two piercers in fluid communication with the cylinders; the housing having an activator movable from a first position to a second position to compress the cylinders to dispense the first and second components to
5 the at least two conduits, and the loading unit having a loading lever movable from a first position to a second position to transfer the first and second components from the vials to the cylinders to replenish the first and second components within the cylinders.

10 A fibrin glue applicator system is provided, in accordance with preferred embodiments, for dispensing a first and a second protein solution. The first and second protein solutions form a biological adhesive when inter-mixed on an application site. The fibrin glue applicator
15 system includes a coupler interface, a disposable loading unit (DLU), and a housing having a handle portion which includes a trigger operatively associated with a slide bar for dispensing the solutions from the DLU. The coupler interface is removably mounted to the DLU and the DLU is
20 removably mounted to the housing.

The DLU includes two piston assemblies for storing the solutions therein before the solutions are dispensed. Each piston assembly includes a cylinder which matingly engages a piston having a rod which translates
25 proximally and distally within the cylinder. The piston assemblies are connected to one another by a loading lever at a proximal end and a dispensing unit at a distal end for holding the assemblies substantially parallel to one another.

30 The coupler interface includes two mounting holes each having a piercer therein for receiving a vial having the first protein solution and a vial having the second protein solution. The protective seal on each vial is

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5 pierced by the piercer within each hole when the vials are
inserted therein. Each piercer is in fluid communication
with one of the cylinders of the DLU via a conduit connected
to a main conduit. A first one-way valve is included within
each conduit to open and close a path leading from the
piercer to the main conduit. The first one-way valves are
forced open by air pressure created when the loading lever
connected to the two pistons of the DLU is translated
proximally causing the protein solutions to be transferred
10 to their corresponding cylinder.

When the protein solutions have been transferred
from the vials to the cylinders of the DLU, the vials and
the coupler interface can be removed from the DLU. The DLU
is then mounted to the housing for dispensing the protein
15 solutions from the cylinders to the application site.

The solutions are dispensed via two dispensing
orifices each in fluid communication with one of the main
conduits. A second one-way valve is fixed within each main
conduit in proximity to each dispensing orifice to open and
close a path leading from each cylinder to its corresponding
20 dispensing orifice. The second one-way valves open when the
solutions are forcibly transferred from the cylinders to the
main conduits. The solutions are forcibly transferred when
the pistons are translated distally by pressing the trigger
of the handle portion to translate the slide bar distally
25 which causes the loading lever to translate distally which
in turn causes the pistons to translate distally thus
creating pressure within the cylinders for dispensing the
solutions within the main conduits. The first and second
30 protein solutions are preferably fibrinogen and thrombin

solutions which intermix on the application site to form a fibrin sealant.

BRIEF DESCRIPTION OF THE DRAWINGS

5 Various embodiments are described herein with reference to the drawings, wherein:

FIG. 1 is a perspective view of a preferred embodiment of a fibrin glue applicator system;

FIG. 2 is a perspective view of the housing showing the elongated body portion and handle portion;

10 FIG. 3 is a perspective view of a disposable loading unit (DLU) having a coupler interface attached thereto;

FIG. 4 is an enlarged cross-sectional view of the DLU and coupler interface with the one-way dispensing and one-way loading valves being in the closed position;

15 FIG. 4A is enlarged view of the one-way loading valve shown in FIG. 4;

FIG. 4B is an enlarged cross-sectional view of the DLU and coupler interface with the dispensing valve in the closed position and the loading valve in the open position;

20 FIG. 4C is an enlarged view of the valves shown in FIG. 4B;

FIG. 5 is an enlarged cross-sectional view of the distal end of the applicator system showing the dispensing valve in the open position and the loading valve in the closed position for dispensing the protein solution; and

25 FIG. 6 is a perspective view showing the protein solutions being dispensed from the fibrin glue applicator system of FIG. 1 as the trigger is depressed.

Attorney Docket: 203-2089DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring to FIGS. 1 through 4A, a fibrin glue applicator system and corresponding parts thereof according to a preferred embodiment of the present disclosure are shown. The applicator system, designated generally by numeral 10, includes a longitudinal housing 12, a disposable loading unit (DLU) 14, and a coupler interface 16. The housing includes an elongated body portion 18 defining a longitudinal axis and a handle portion 20.

The handle portion 20 includes a trigger 22 configured to pivot with respect to the handle portion 20. The trigger includes a grip portion 24 extending downwardly and adapted to be pressed by the fingers of a user's hand to actuate the applicator system 10 to dispense protein solutions within the DLU 14 as further described below.

The elongated body portion 18 includes a rounded proximal end 26 and a flat surface 28 extending from above the handle portion 20 to a distal end 30. A pair of flanges 32 extend perpendicular to the longitudinal axis at the distal end 30 and a slot 34 is formed at the mid-point of the elongated body portion 18.

Elongated body portion 18 further includes a slide bar 36 having two apertures 38 and a slot 40 adjacent thereto. The slide bar 36 is operatively associated with the trigger 22 for distal and proximal translation of the slide bar 36 along a chamber 42 of the elongated body portion 18 as the trigger 22 is moved proximally and distally, respectively. The trigger 22 may be operatively associated with the slide bar 36 by any conventional mechanism, such as a mechanism having rotatable gears and/or movable rods. It is contemplated to provide a ratchet

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mechanism having notches on an upper portion of the trigger 22 to control the amount of movement of the trigger 22 and hence the slide bar 36.

5 The DLU 14 includes two piston assemblies 44 each having a cylinder 46, a piston 48 having a rod 50 connected to a stopper 52 at a proximal end. As shown by FIG. 3, a loading lever 54 connects each stopper 52 to one another to effect simultaneous movement of each rod 50 when the loading lever 54 is translated proximally to transfer the solutions
10 from the vials 56 to the cylinders 46 as described below.

The DLU 14 further includes a dispensing unit 58 having two main conduits 60 therein each in fluid communication with a corresponding cylinder 46 at a proximal end and a dispensing orifice 62 at a distal end as shown by
15 the cross-sectional view of FIG. 4. The dispensing unit 58 further includes two conduits 64 perpendicular to the two main conduits 60. The two conduits 64 are in fluid communication with a corresponding piercer 66 and a corresponding main conduit 60.

20 With reference to FIG. 3, the coupler interface 16 includes two holes 80 for receiving the vials 56 containing solutions of fibrinogen and thrombin which form a fibrin sealant when intermixed on an application site. Each piercer 66 of the dispensing unit 58 aligns with a
25 corresponding hole 80 for piercing the protective seal 81 on each vial 56 when the vial 56 is inserted within the hole 80. As noted above each piercer 66 is in fluid communication with a conduit 64 connected to one of the main conduits 60 within the dispensing unit 58 for transferring
30 the fibrinogen and thrombin solutions to a corresponding cylinder 46.

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5 A one-way loading valve 68 is included within each conduit 64 which opens when the loading lever 54 is moved proximally as described below with reference to FIGS. 4B and 4C. A one-way dispensing valve 70 is included within each main conduit 60 which opens when the trigger 22 is pressed as described below with reference to FIGS. 5 and 6.

10 As shown by FIGS. 4 and 4A, each one-way valve includes a pointed tip 69 attached to a spring 71. The pointed tip 69 engages a mouth 73 of a conduit to prevent fluid flow in a first position and the pointed tip 69 disengages the mouth 73 of the conduit to permit fluid flow in a second position. The pointed tip 69 disengages the mouth 73 of the conduit when pressure is applied within the conduit by either translating the pistons 48 proximally to open the loading one-way valves 68 or distally to open the dispensing one-way valves 70 as described below with reference to FIGS. 4B to 5. The loading and dispensing one-way valves are both closed when the loading lever 54 is stationary or the trigger 22 is in the inactivated position.

20 Two notches 72 are included on two opposing faces 74 of the dispensing unit 58 which are used to snap-fit the dispensing unit 58 with the flanges 32 of the elongated body portion 18 to secure the DLU 14 to the housing 12. The DLU 14 is further secured to the housing 12 by two tabs 76 which are fitted around each piston rod 50 and are adapted to be press-fitted to the slot 34 on the flat surface 28 of the elongated body portion 18. In addition, a portion of the rods 50 and stoppers 52 of the pistons 48 are positioned within the two apertures 38 and slot 40 of the slide bar 36 to further secure the DLU 14 to the housing 12.

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As shown by the cross-sectional view of FIG. 4, a spring mechanism 82 is included in proximity to each hole 80 of the coupler interface 16. The spring mechanism 82 includes two springs 84 and detents 88 attached thereto at opposing sides of the coupler interface 16 and equidistant from the piercer 66 for engaging the neck 86 of the vial 56 for locking and holding the vial 56 in position. It is contemplated to provide a safety door mechanism in proximity to each piercer 66 which would include safety doors which close above each piercer 66 when the vials 56 are removed from the coupler interface 16 to prevent the user from being accidentally pierced by the piercers 66.

The operation of the applicator system 10 will now be described with reference to FIGS. 4B to 6. As shown by FIG. 4B, the vial 56 is placed within the hole 80 to pierce the protective seal 81 by the piercer 66. The piston 48 is then translated proximally to create proximal air pressure from the tip of the piercer 66 to the interior of the cylinder 46, thereby disengaging the pointed tip 69 of the loading one-way valve 68 from the mouth 73 of the conduit 64 to transfer the protein solution within the cylinder 46. The enlarged view of FIG. 4C illustrates the disengagement of the pointed tip 69 of the loading one-way valve 68 from the mouth 73 of the conduit 64 as air pressure is created within the conduit 64. It is noted that both protein solutions are simultaneously transferred from their respective vial 56 to a corresponding cylinder 46 as the pistons 48 are simultaneously translated proximally.

Once the protein solutions have been transferred to their corresponding cylinders 46, the loading lever 54, the vials 56, and the coupler interface 16 can be removed

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from the DLU 14. The DLU 14 is then secured to the housing 12 as discussed above. The user can then bring the housing 12 with the DLU 14 attached thereto in proximity to a surgery site or a wound for dispensing the solutions to form a fibrin sealant over the surgery site or wound.

The protein solutions are dispensed simultaneously as the trigger 22 is pressed by the user's fingers to cause the slide bar 36 to translate distally thereby forcing the pistons 48 to translate within the cylinders 46 to force the solutions to be dispensed within the main conduits 60. As each solution is dispensed within one of the main conduits 60, pressure is created upon the pointed tip 69 of each dispensing one-way valve 70 causing the pointed tip 69 to be disengaged from the mouth 73 of each main conduit 60 as shown by FIG. 5 to permit each solution to be dispensed from its respective dispensing orifice 62 as shown by FIG. 6.

It is contemplated that the present invention may be packaged as a kit for applying a solution of fibrinogen and a solution of thrombin on a wound to stop bleeding or the like. The kit may include the housing 12, the DLU 14, the coupler interface 16, and the dispensing unit 58.

It is understood that various modifications may be made to the embodiments disclosed herein. Also, besides applying solutions of fibrinogen and thrombin to form a fibrin sealant, the fibrin glue applicator system can be used to perform human or veterinary surgical procedures including applying antiseptics, medication and other similar procedures. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments.

CLAIMS:

1. An applicator system for dispensing from respective dispensing orifices at least two components for forming a multicomponent biological adhesive, the applicator system comprising:

a housing configured to receive a loading unit having at least two piston assemblies, each of said at least two piston assemblies having a piston matingly engaging the proximal end of a cylinder configured for retaining one of said at least two components, and for dispensing said one component through a distal end of said cylinder; and

an activator assembly provided on said housing having an activator movable from a first position to a second position to compress each of said at least two pistons to dispense said at least two components through said at least two conduits in said dispensing unit; and characterized by:

a dispensing unit having at least two conduits which in use are in fluid communication with the respective distal ends of said cylinder of said at least two piston assemblies and with respective ones of said dispensing orifices, said dispensing unit including a coupler interface having at least two piercers.

2. The applicator system according to claim 1, wherein said coupler interface is configured for receiving two vials each storing one of said at least two components and wherein proximal translation of each piston causes a valve in proximity to each of said at least two piercers to move from a closed position to an open position for transferring said at least two components from said vials to said cylinders.

3. The applicator system according to claim 1 or 2, wherein said dispensing unit includes a valve within each of said at least two conduits configured to move from a closed position to an open position when said activator is moved from said first position to said second position.

4. The applicator system as claimed in any one of claims 1 to 3, wherein

said coupler interface has a conduit assembly having a first pair of conduits in fluid communication with said at least two piercers and a pair of main conduits, said conduit assembly having a second pair of conduits in fluid communication with a pair of said dispensing orifices and said pair of main conduits, said pair of main conduits being, in use, in fluid communication with said at least two piston assemblies; and

said activator assembly in use compresses each of said at least two piston assemblies to dispense said at least two components through said pair of main conduits, said second pair of conduits, and said pair of dispensing orifices.

5. The applicator system according to any one of claims 1 to 4, including said loading unit.

6. The applicator system according to any one of claims 1 to 5, wherein said activator assembly includes control structure for restricting said activator from returning to said first position after the activator is moved from said first position.

7. The applicator system according to claim 6, wherein said control structure includes a ratchet

mechanism.

8. The applicator system according to claim 4, including said at least two components, of which one is a thrombin solution and another of said at least two components is a fibrinogen solution, whereby said multicomponent biological adhesive is a fibrin sealant.

9. A manually-operated applicator for dispensing a first and second component of a biological adhesive, the applicator comprising:

a conduit assembly having a first pair of conduits and a first valve movable from a closed position to an open position;

a piston assembly having a first cylinder containing the first component and a second cylinder containing the second component, the first cylinder being in communication with a first of said first pair of conduits and the second cylinder being in communication with a second of said first pair of conduits;

an activator assembly having an activator for imparting distal pressure to said first and second cylinders to effect dispensing of said first and second components to said first pair of conduits and move said first valve from said closed position to said open position; and

a coupler interface in engagement with said conduit assembly and configured to receive, in use, at least two vials storing said first and second components for replenishing said first and second cylinders.

10. The manually-operated applicator according to claim 9, wherein said coupler interface further includes

a pair of piercers in fluid communication with a second pair of conduits in said conduit assembly to effect transferring of said first and second components from said vials to said first and second cylinders upon imparting proximal pressure to said first and second cylinders.

11. The manually-operated applicator according to claim 9 or 10, wherein each of said second pair of conduits includes a second valve configured to move from a closed position to an open position upon imparting proximal pressure to said first and second cylinders.

12. The manually-operated applicator according to any one of claims 9 to 11, including said first component which is a thrombin solution and said second component which is a fibrinogen solution, whereby said biological adhesive is a fibrin sealant.

13. A kit for dispensing from respective vials a first and second component of a biological adhesive, the kit comprising:

- a loading unit having at least two piston assemblies, each of said at least two piston assemblies having a piston matingly engaging a cylinder configured for retaining one of said first and second components;

- a housing configured to receive said loading unit;

- a dispensing unit having at least two conduits in fluid communication with said cylinders;

- a coupler interface configured for receiving the said respective vials storing said first and second components therein, said coupler interface having at least two piercers in fluid communication with said cylinders;

- said housing having an activator movable from a first

position to a second position to compress said cylinders to dispense said first and second components to said at least two conduits, and said loading unit having a loading lever movable from a first position to a second position to transfer said first and second components from said vials to said cylinders to replenish said first and second components within said cylinders.

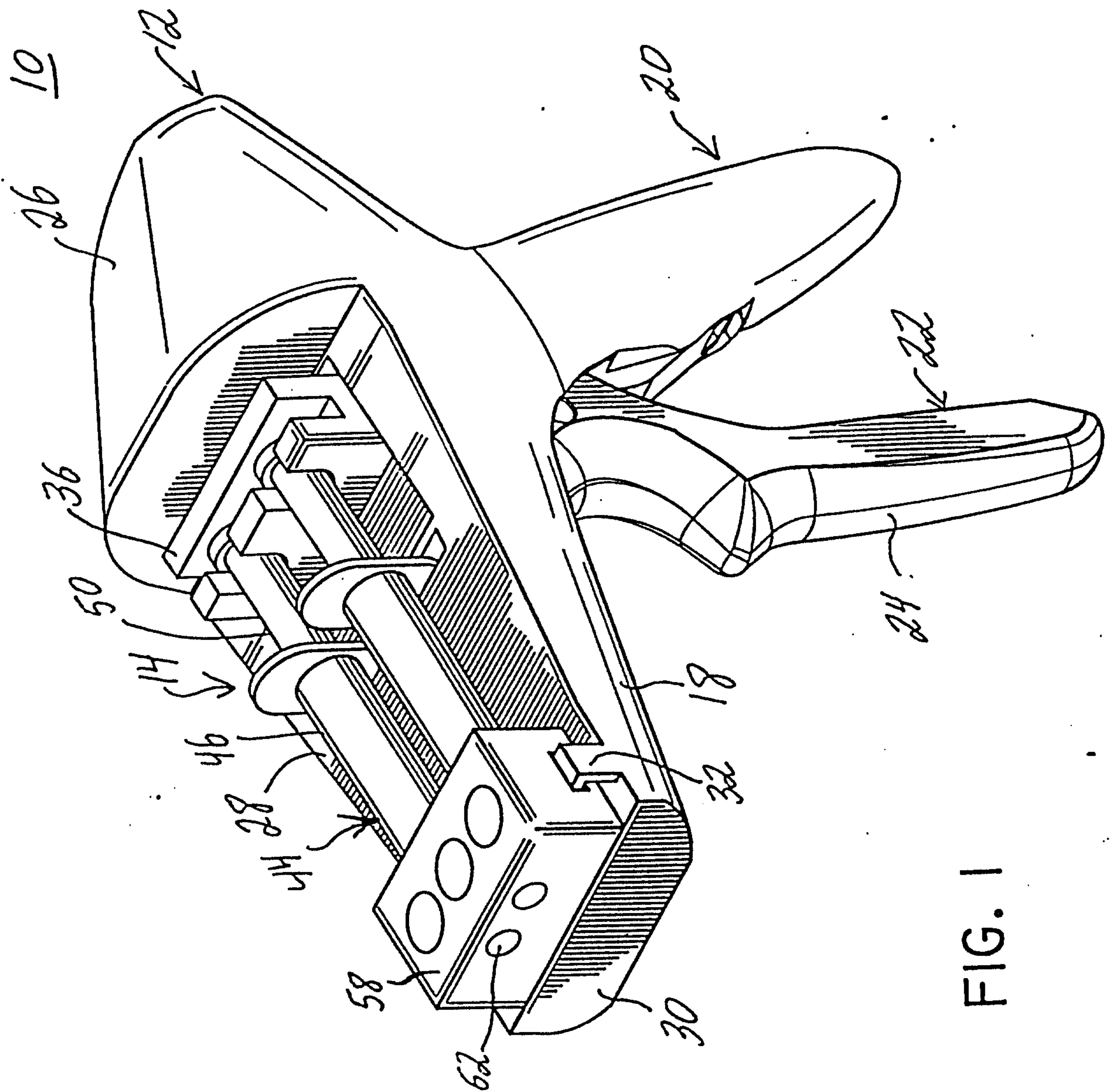


FIG. 1

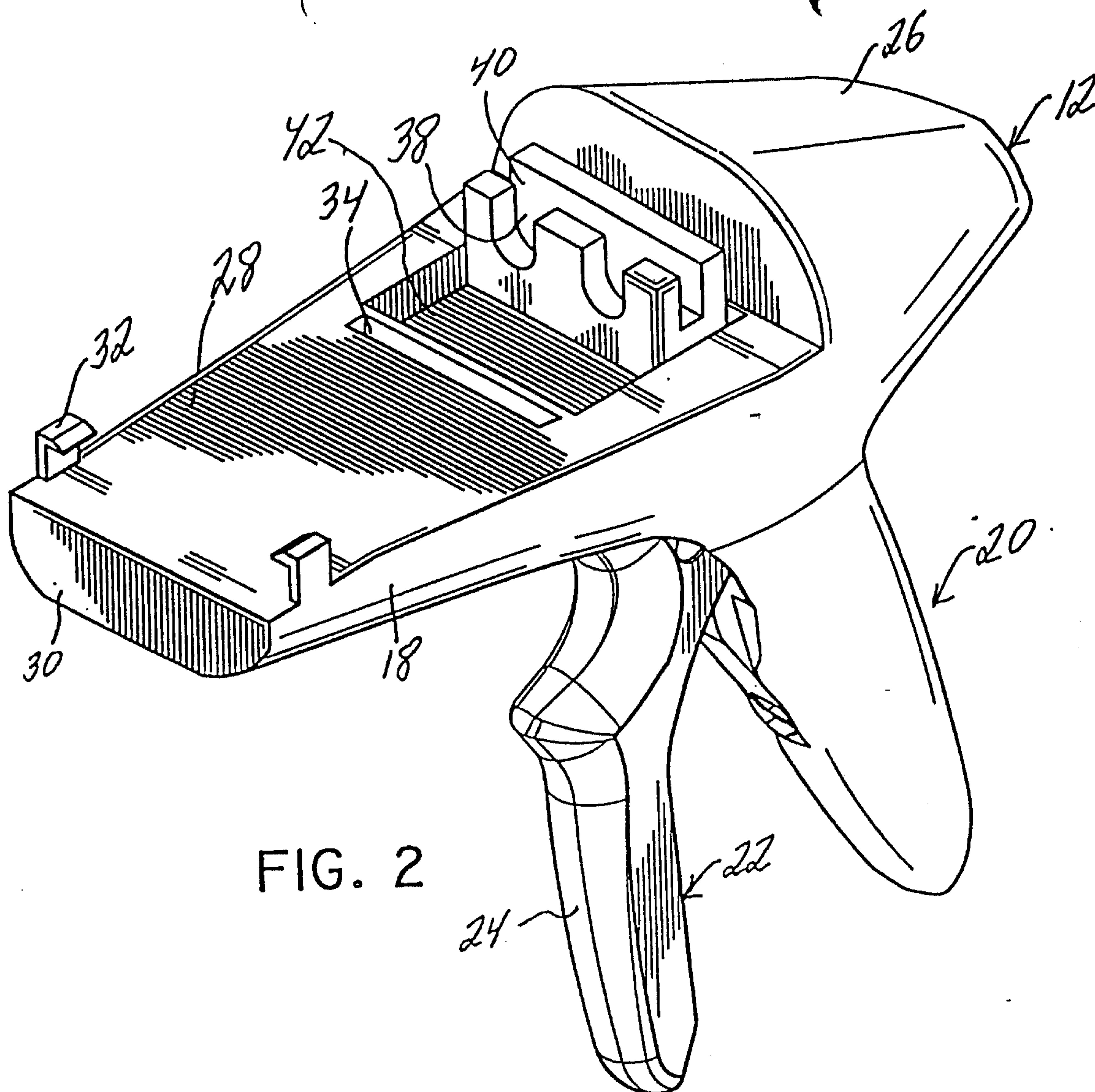


FIG. 2

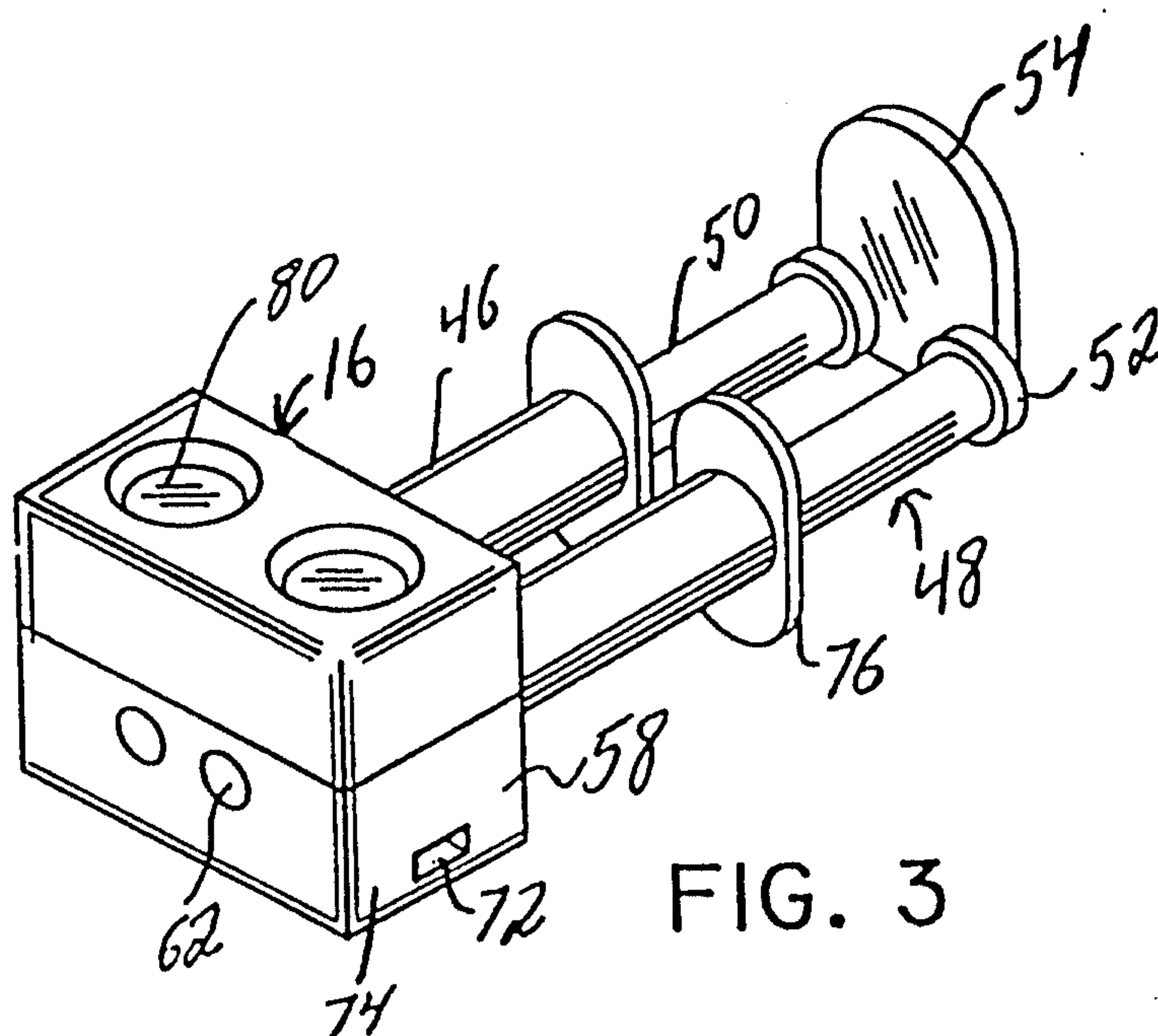
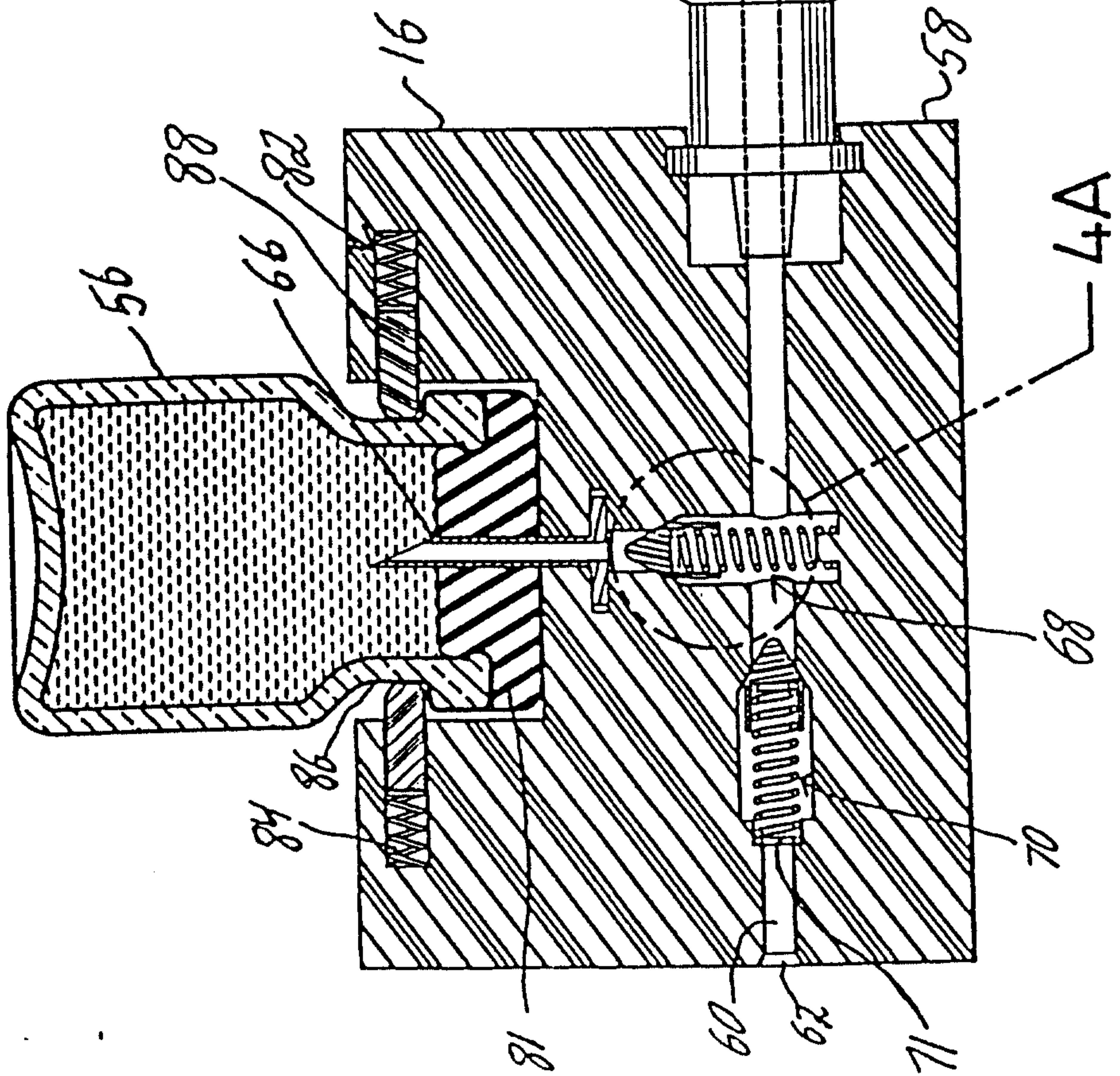
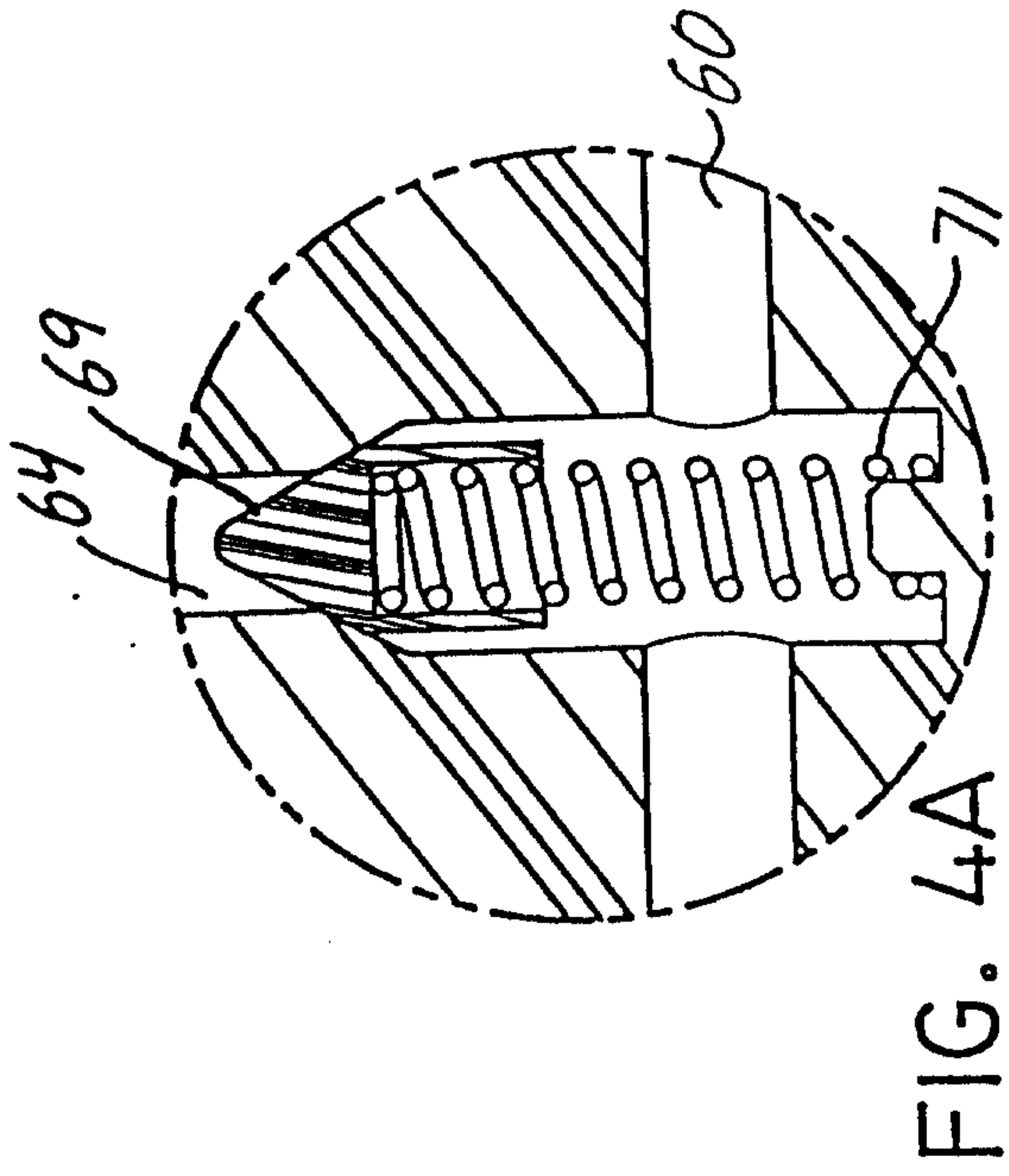


FIG. 3



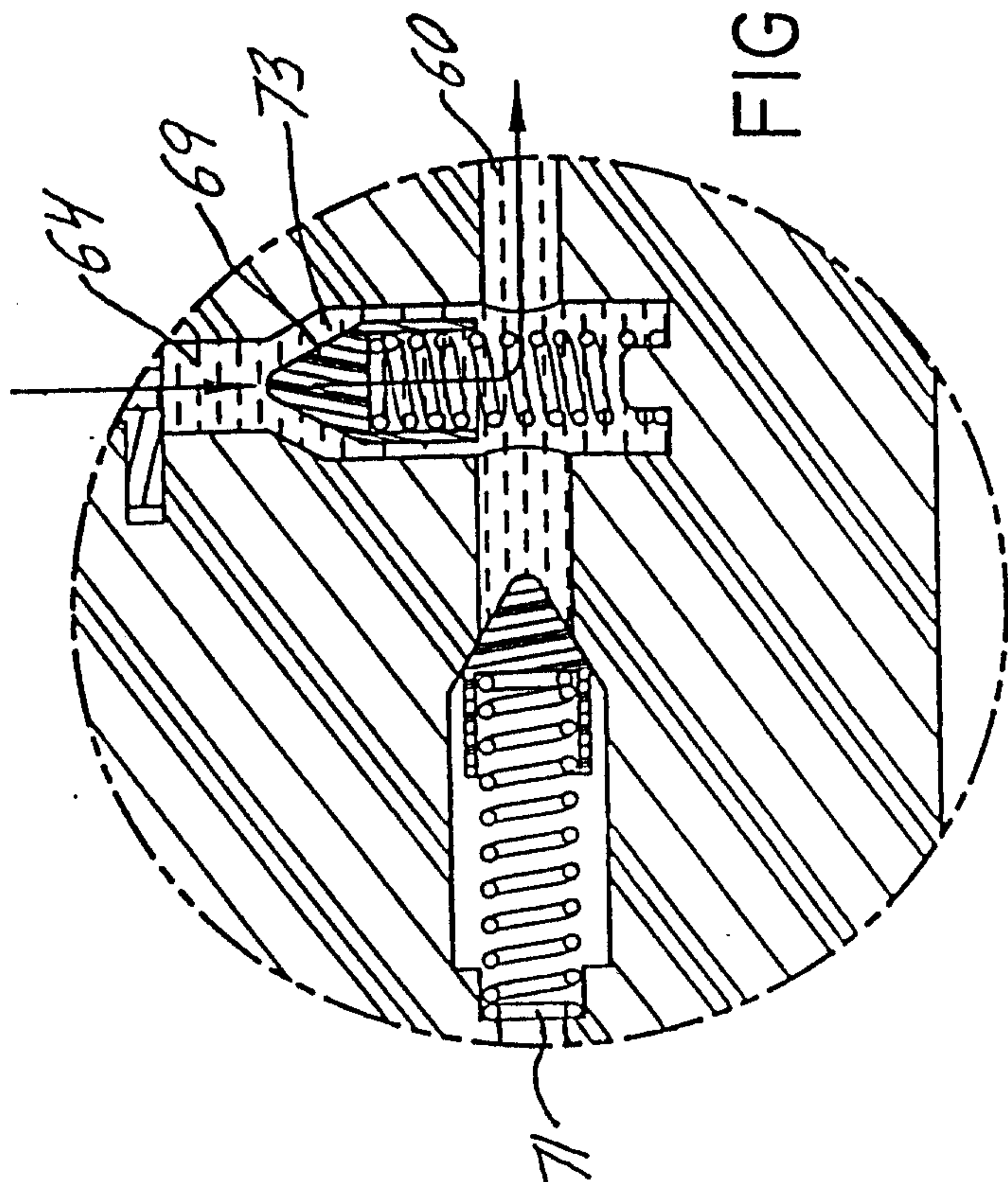


FIG. 4C

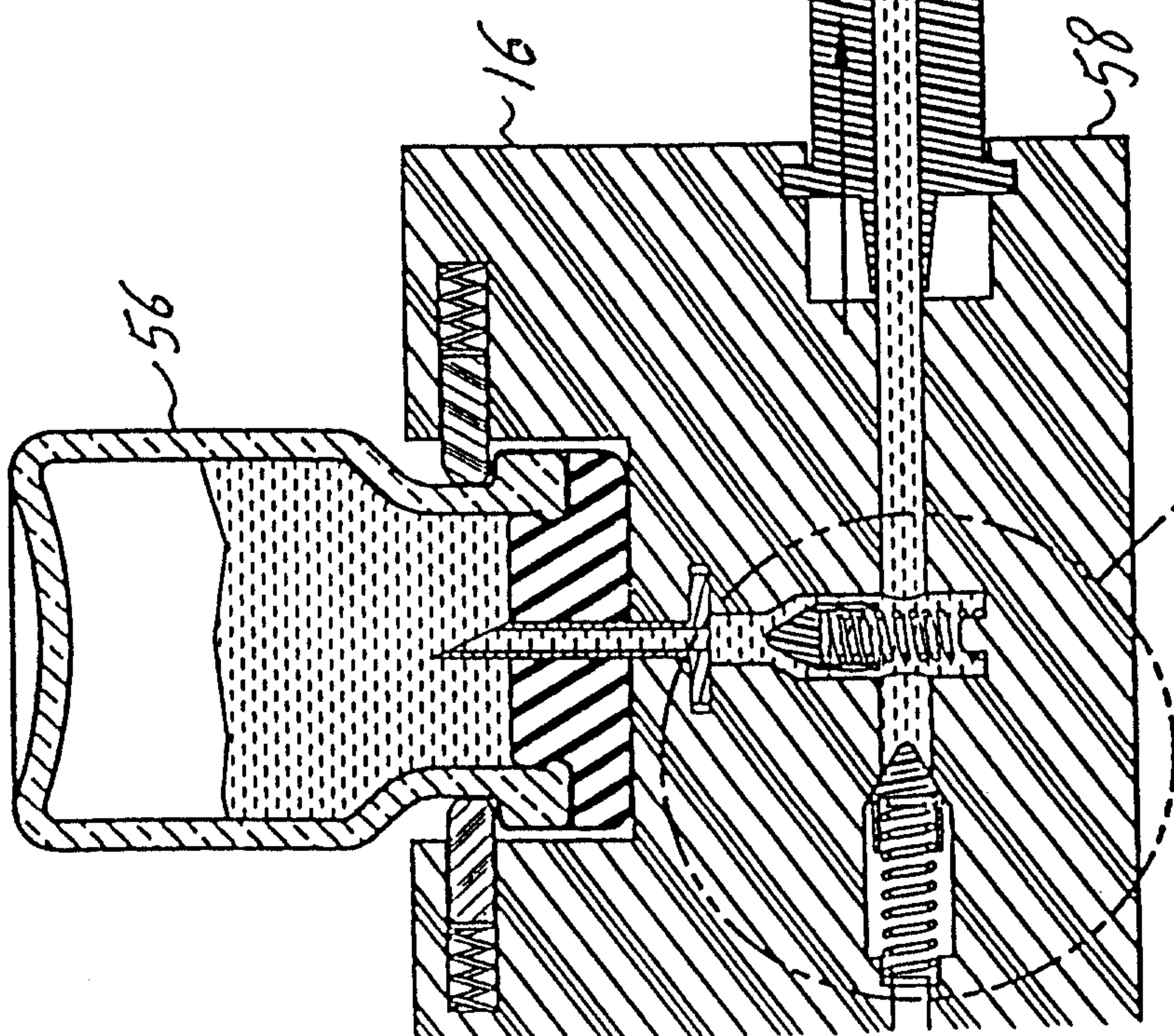


FIG. 4B

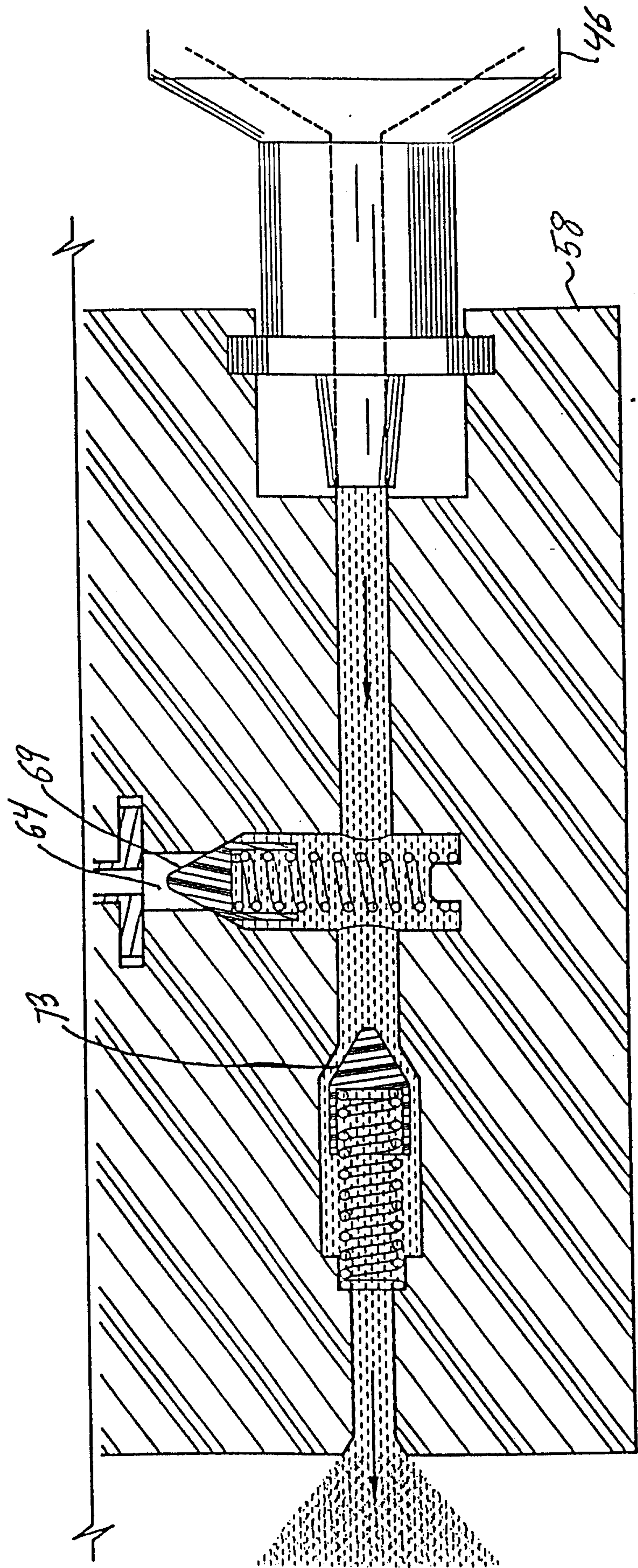


FIG. 5.

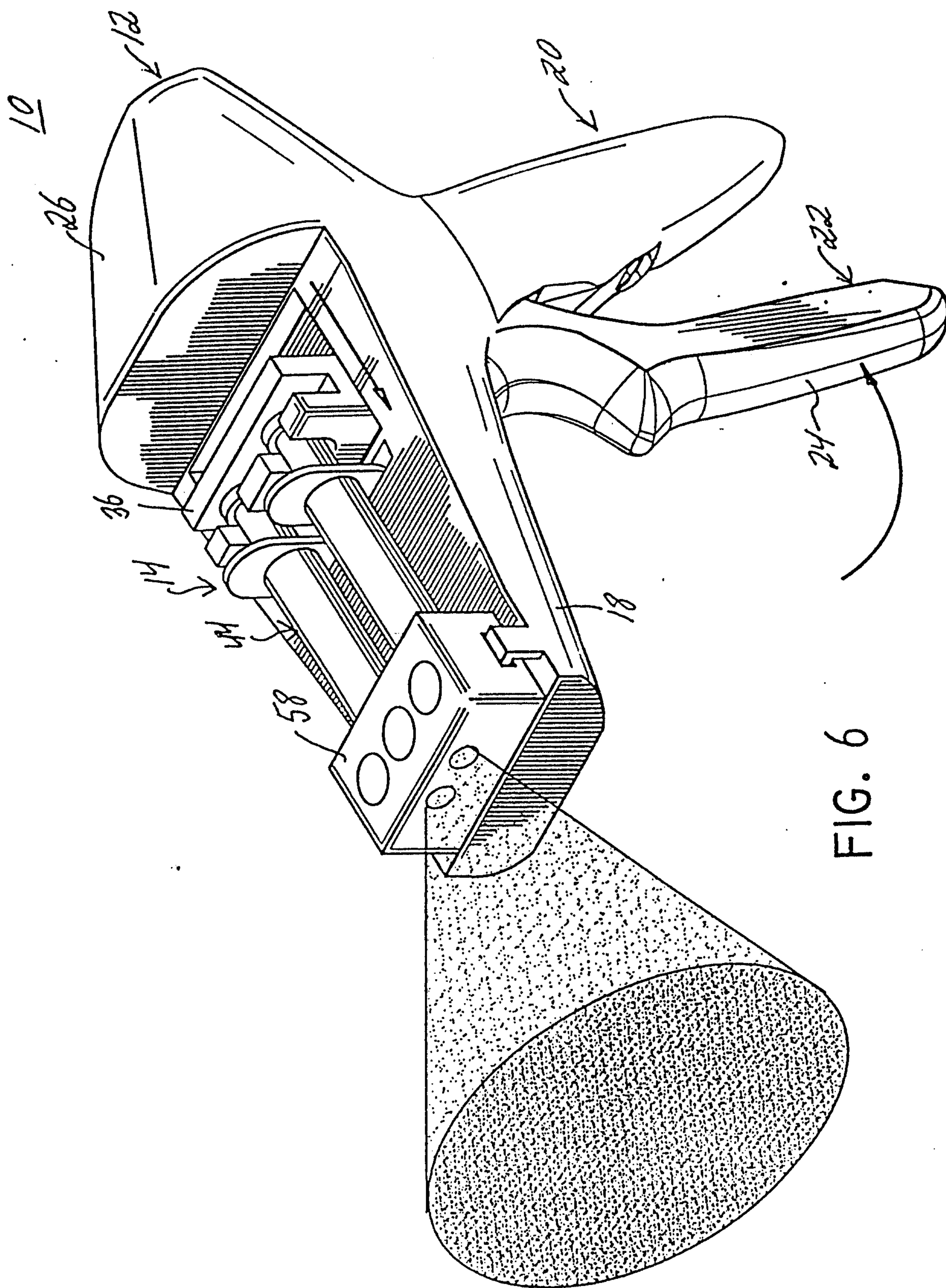


FIG. 6

