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(54) FIBRIN SEALANT APPLICATOR SYSTEM

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Related U.S. Application Data

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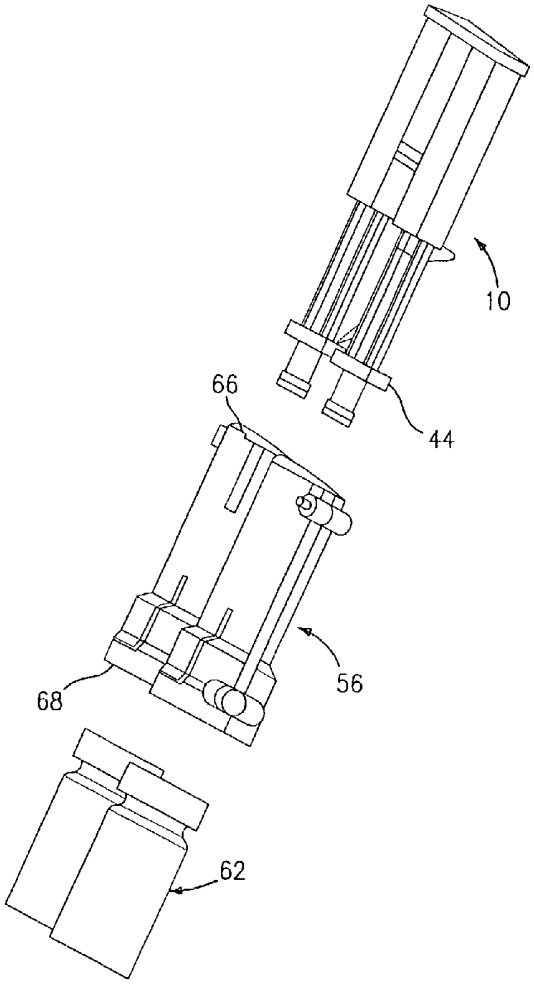
(51) **Int. Cl.**[7] **A61M 5/00**

(52) **U.S. Cl.** **604/191**; 604/82; 606/214

(57) ABSTRACT

Fibrin sealant applicator systems are provided for dispensing a first and a second protein solution to form a biological adhesive which overcome the disadvantages of the prior art. The first and second protein solutions are preferably fibrinogen and thrombin solutions which may intermix on an application site or within the applicator to form a fibrin sealant. The fibrin sealant applicator systems according to the present disclosure include two piston-type sub-assemblies coupled to two vials storing the fibrinogen and thrombin via a coupling unit. The piston-type sub-assemblies store sterilized water within reservoirs which are in fluid communication with the vials via the coupling unit. The water is forced into the vials to form the fibrinogen and thrombin solutions. The solutions are then drawn into the reservoirs and a Y-coupler is attached to the distal end of the piston-type sub-assemblies The Y-coupler provides fluid communication between the reservoirs and a nozzle body for dispensing the solutions when distal pressure is created within the reservoirs to force the solutions towards the nozzle body.



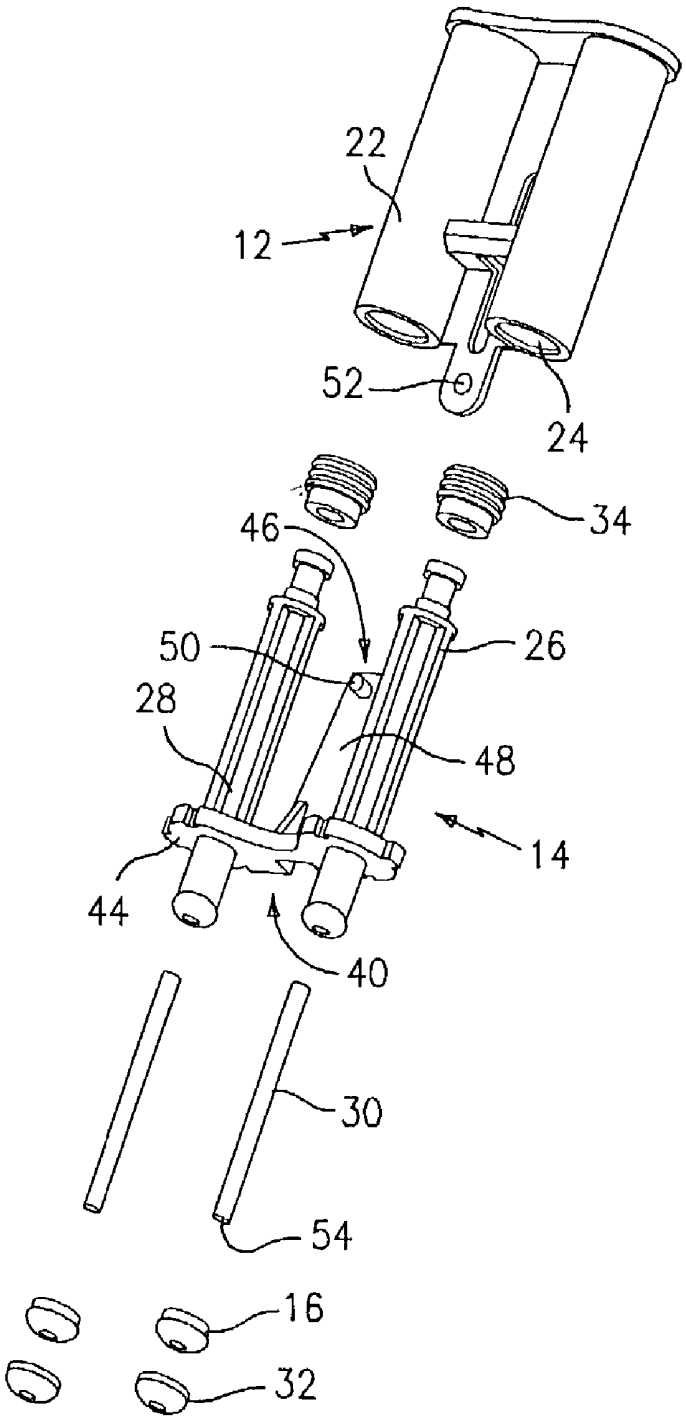


FIG. 1A

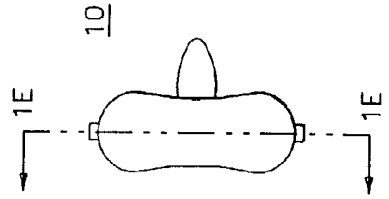


FIG. 1D

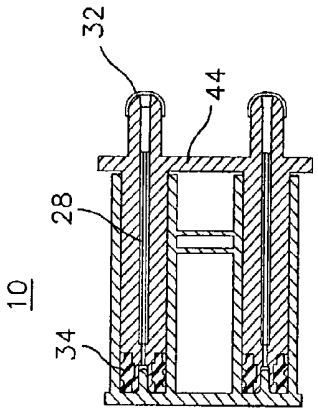


FIG. 1E

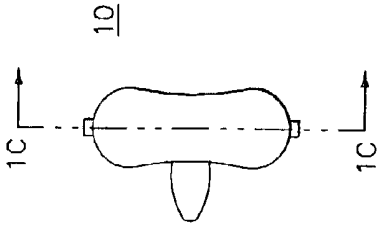


FIG. 1B

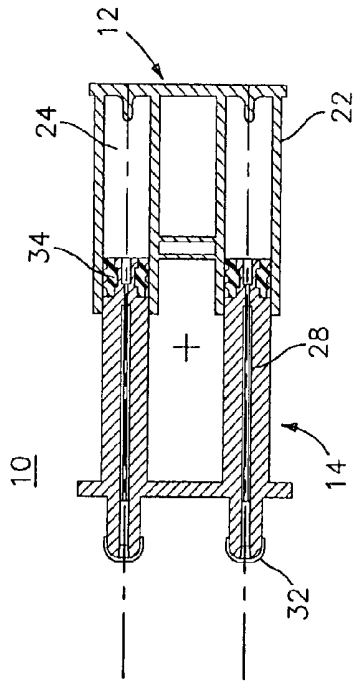


FIG. 1C

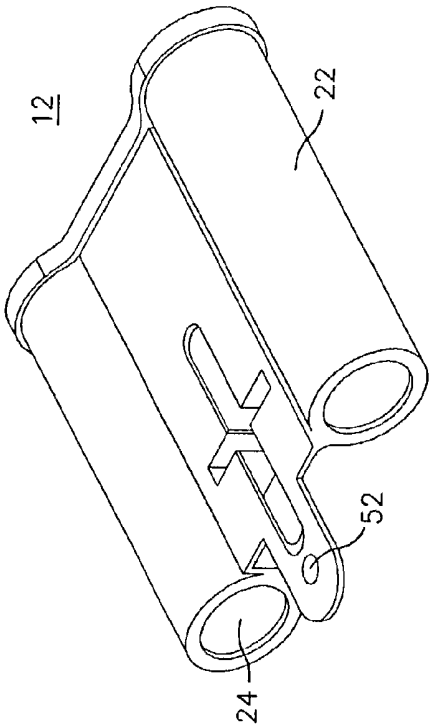


FIG. 2A

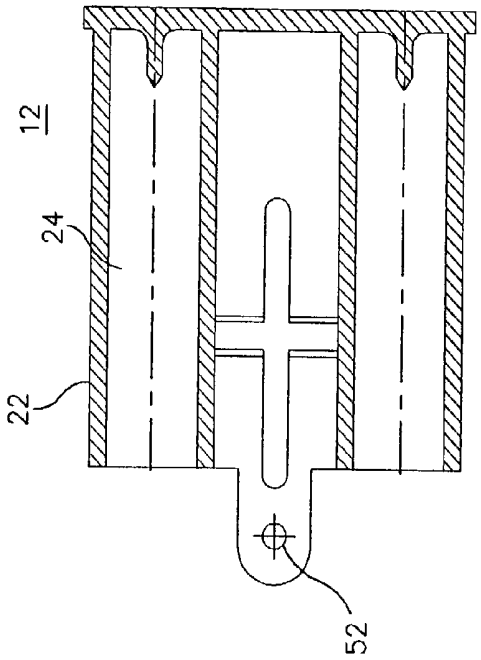


FIG. 2C

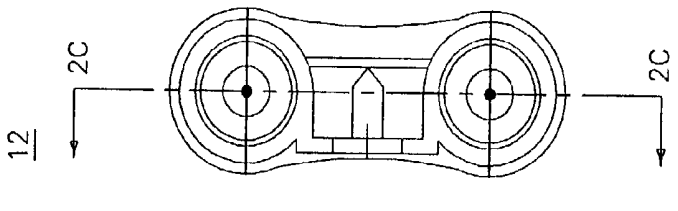


FIG. 2B

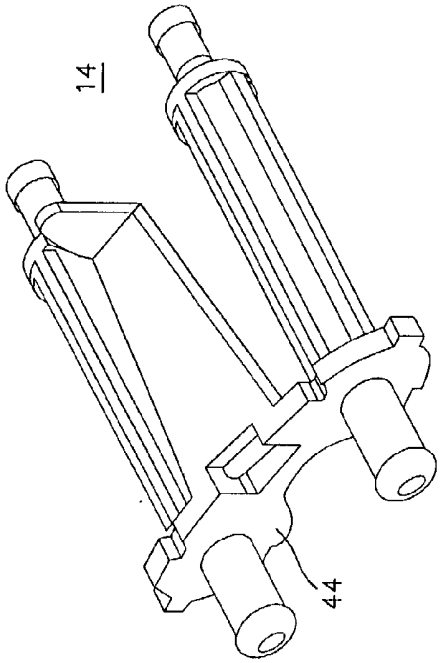


FIG. 3A

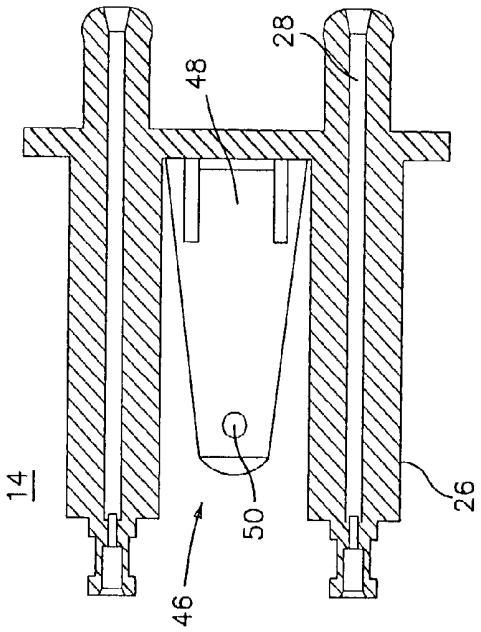


FIG. 3C

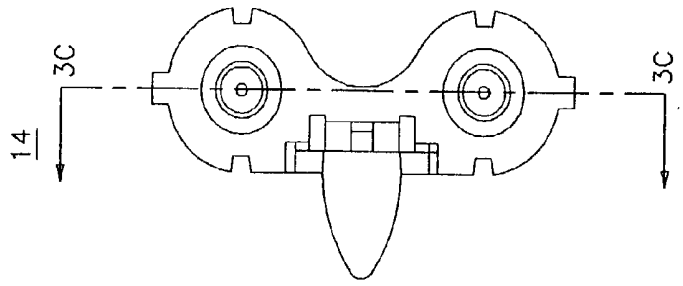


FIG. 3B

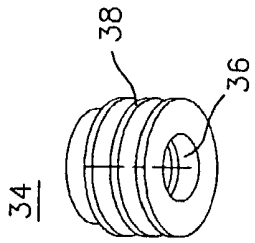


FIG. 5A

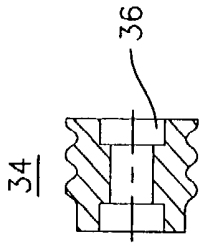


FIG. 5C

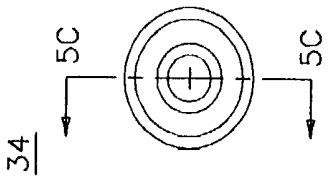


FIG. 5B

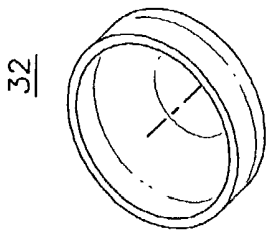


FIG. 4A

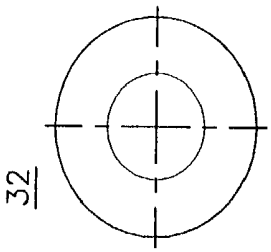


FIG. 4B

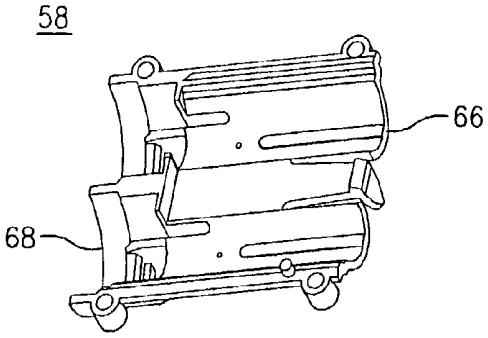


FIG. 6A

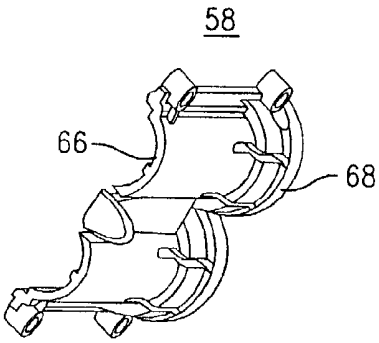


FIG. 6B

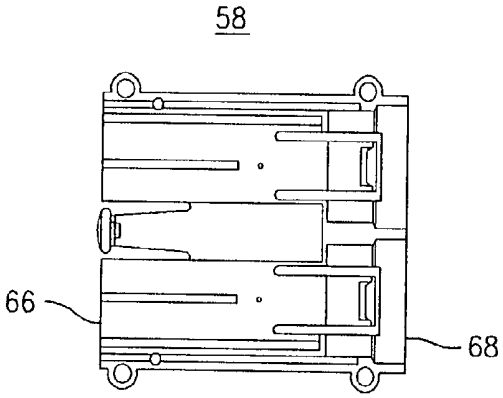


FIG. 6C

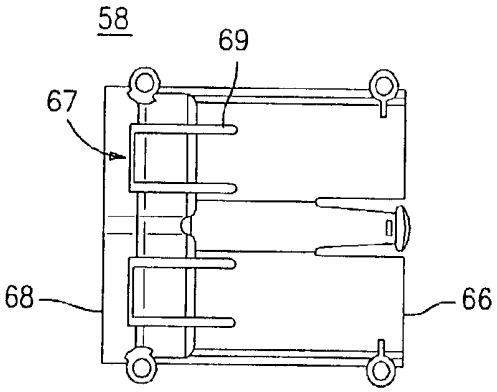


FIG. 6D

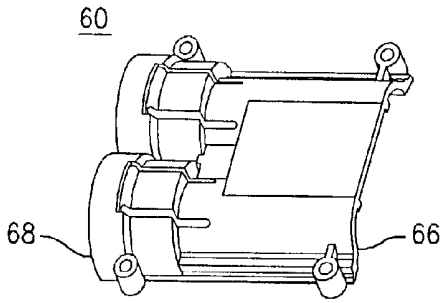


FIG. 7A

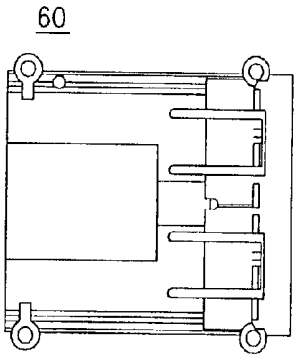


FIG. 7B

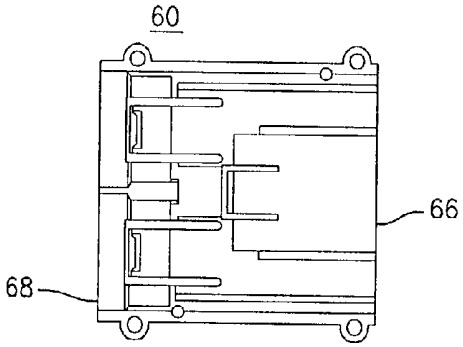


FIG. 7C

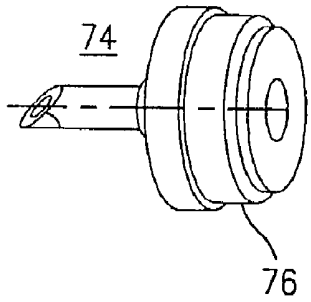


FIG. 8A

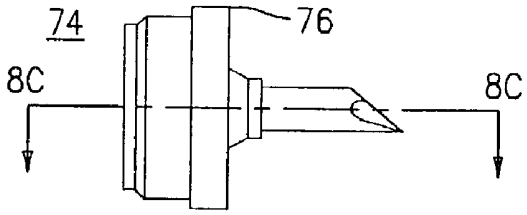
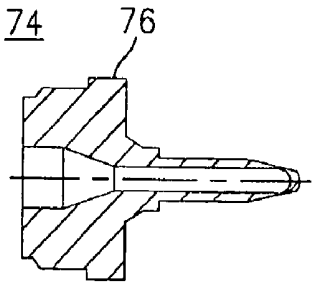


FIG. 8B



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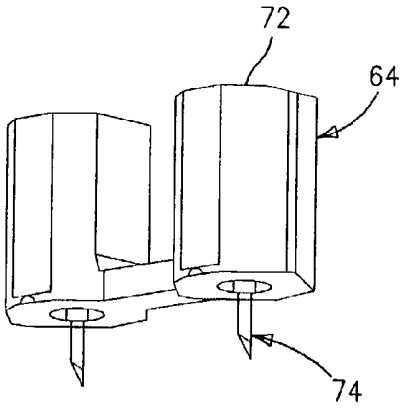


FIG. 9A

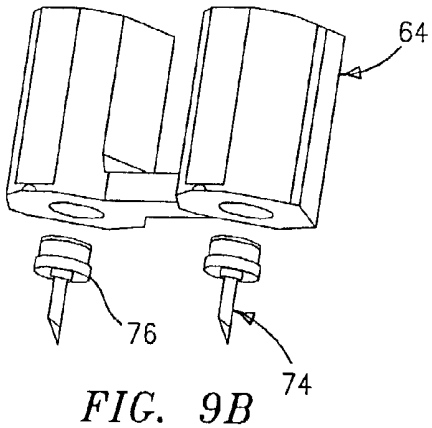


FIG. 9B

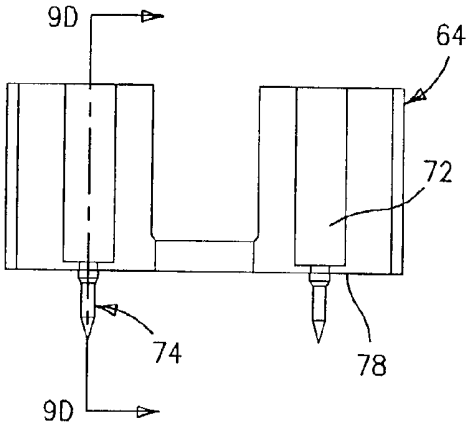


FIG. 9C

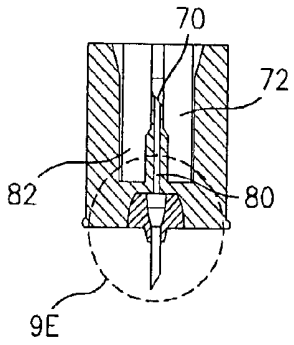


FIG. 9D

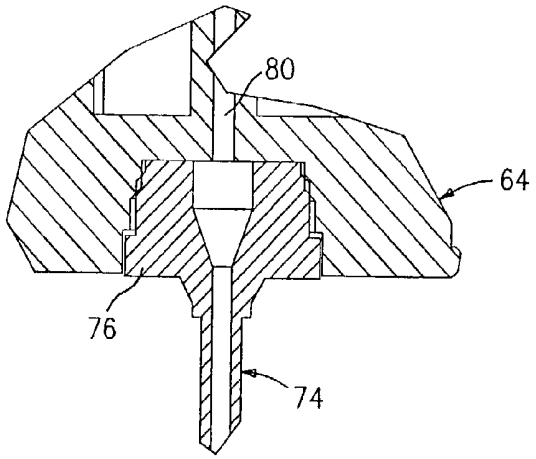


FIG. 9E

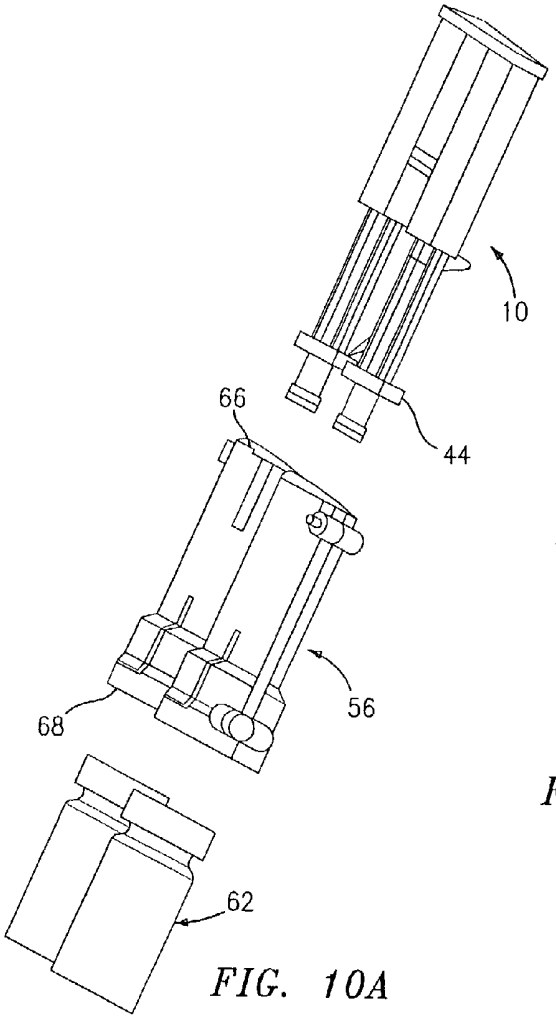


FIG. 10A

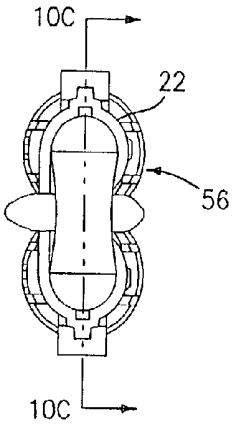


FIG. 10B

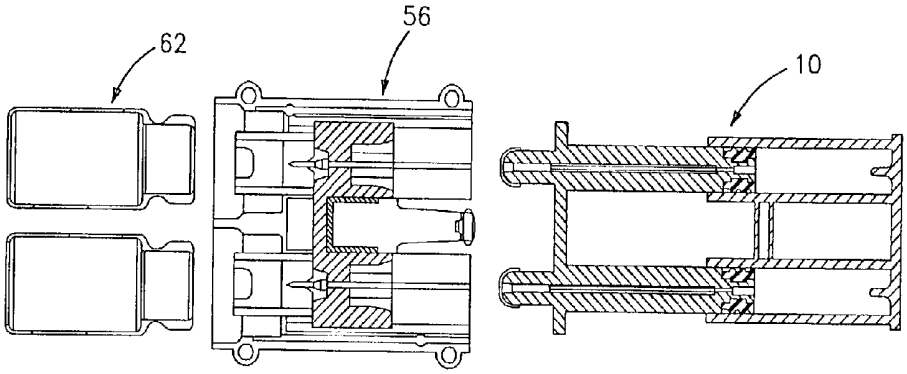
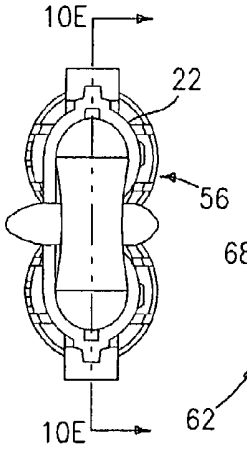


FIG. 10C



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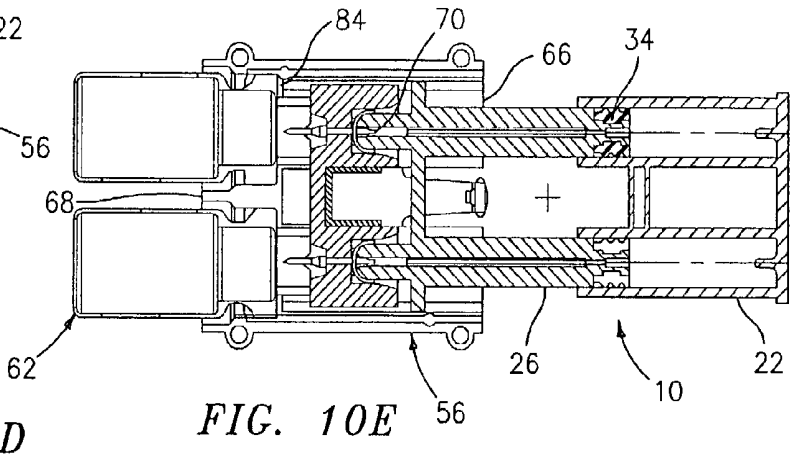

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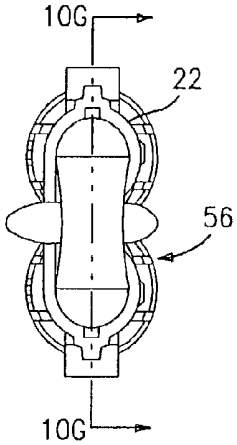

FIG. 10F

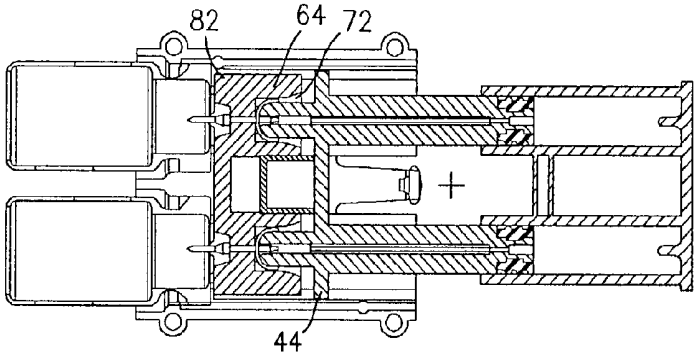

FIG. 10G

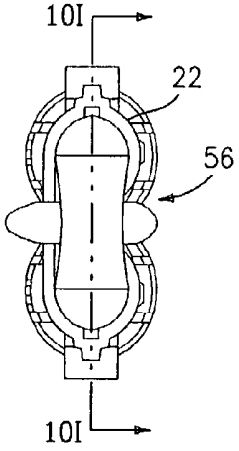

FIG. 10H

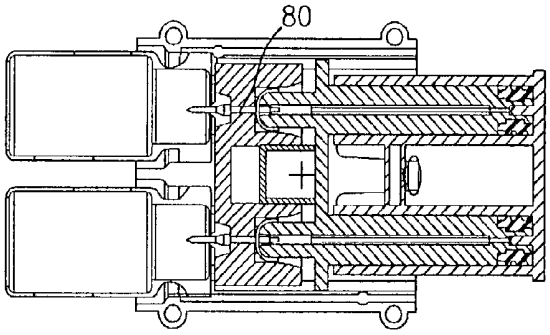

FIG. 10I

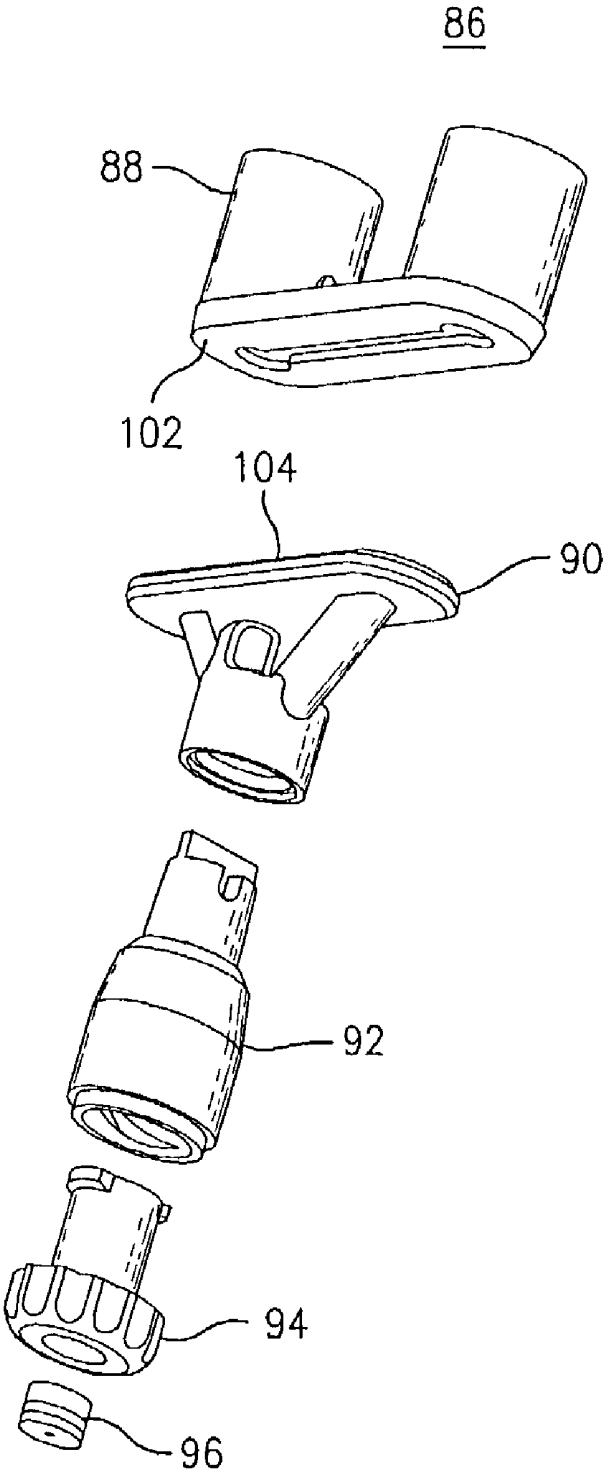

FIG. 11A

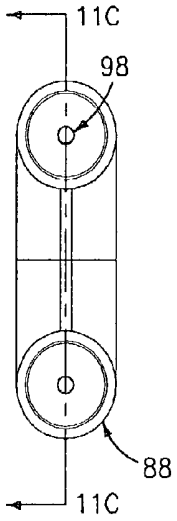

FIG. 11B

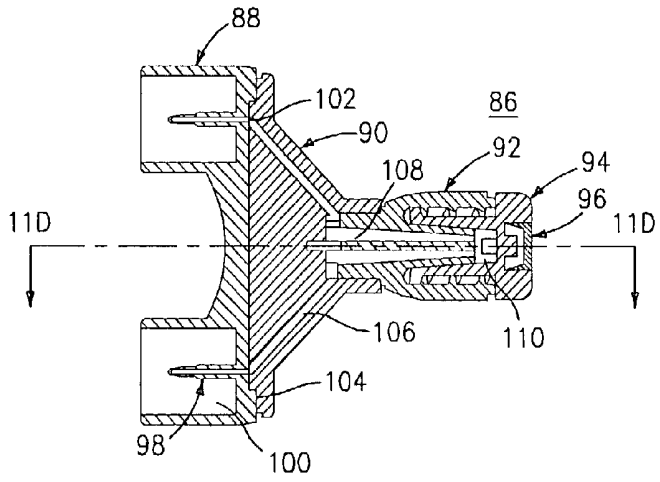

FIG. 11C

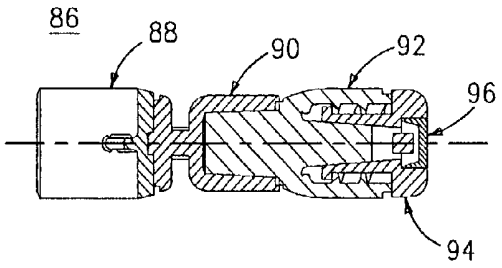

FIG. 11D

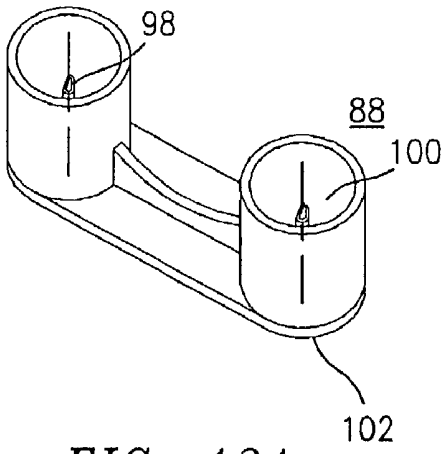

FIG. 12A

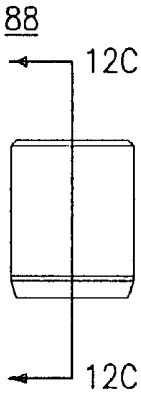

FIG. 12B

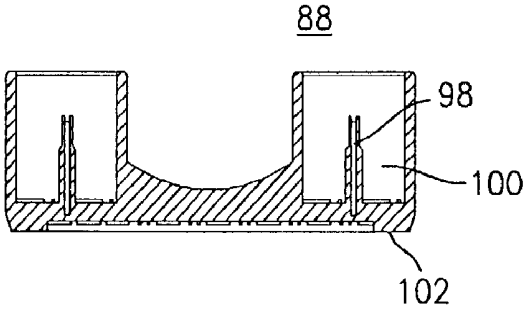

FIG. 12C

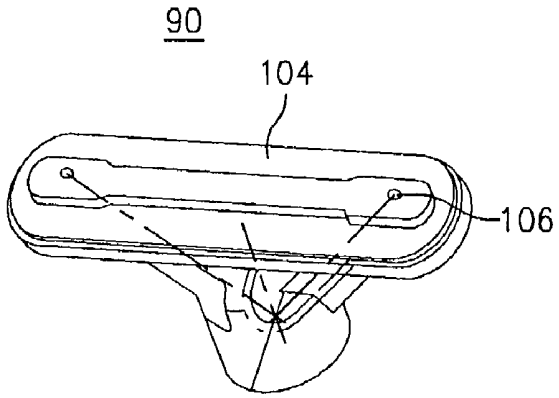

FIG. 13A

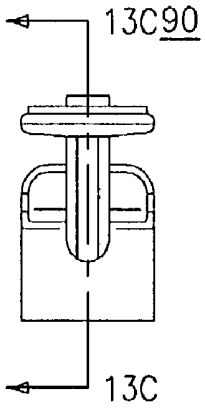

FIG. 13B

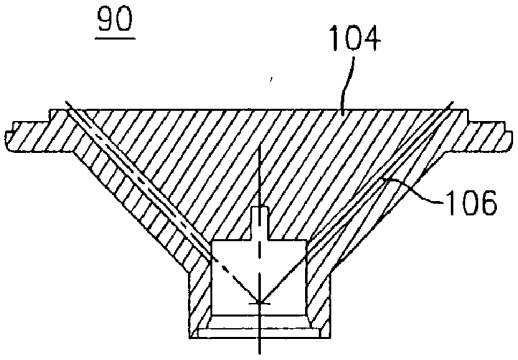

FIG. 13C

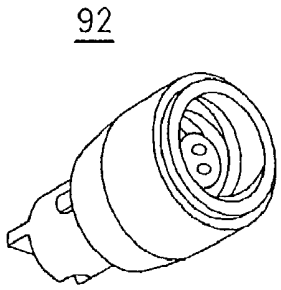

FIG. 14A

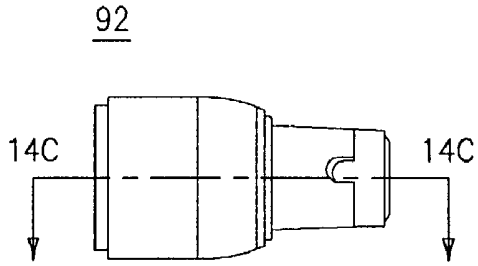

FIG. 14B

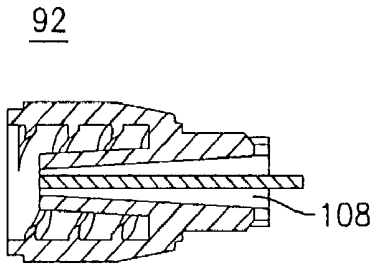

FIG. 14C

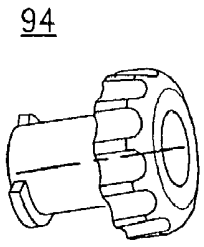

FIG. 15A

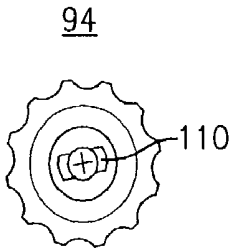

FIG. 15B

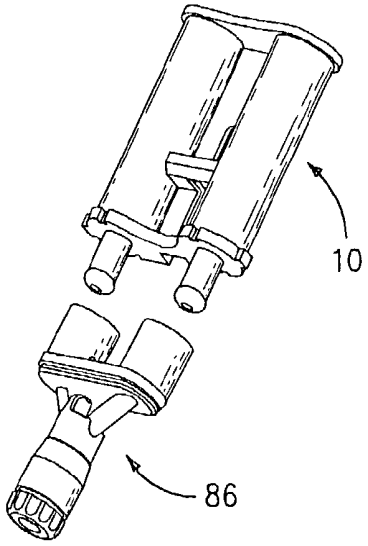

FIG. 16A

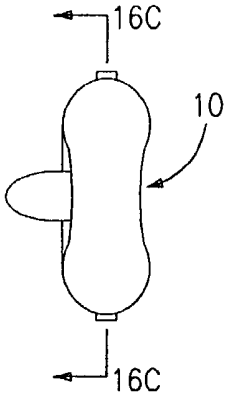

FIG. 16B

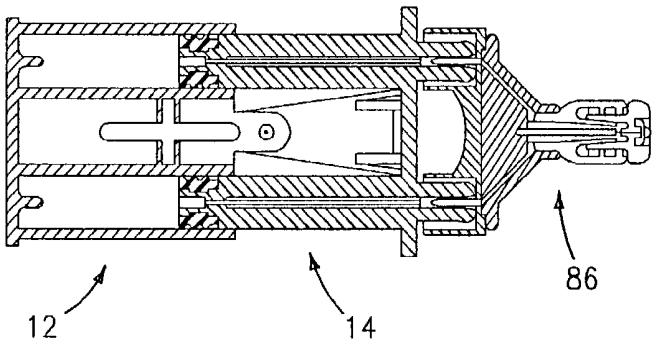

FIG. 16C

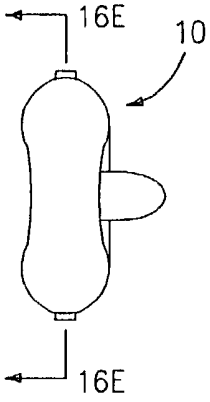

FIG. 16D

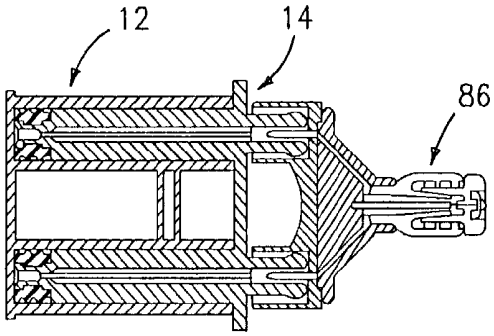

FIG. 16E

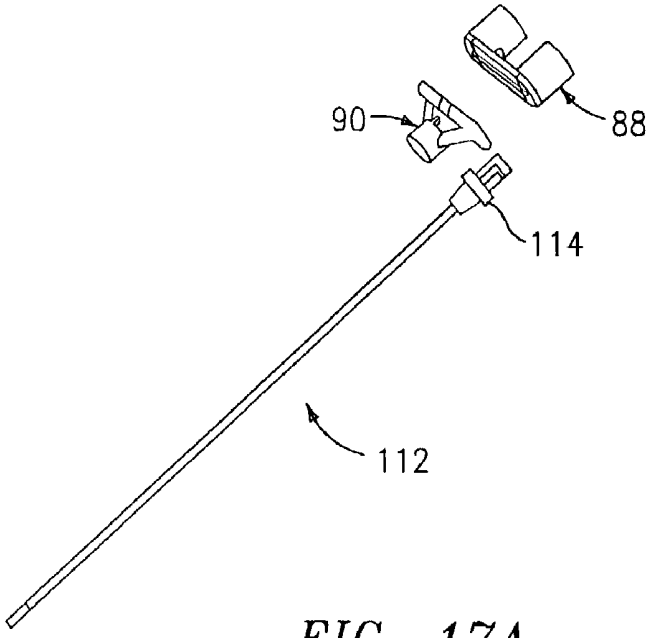

FIG. 17A

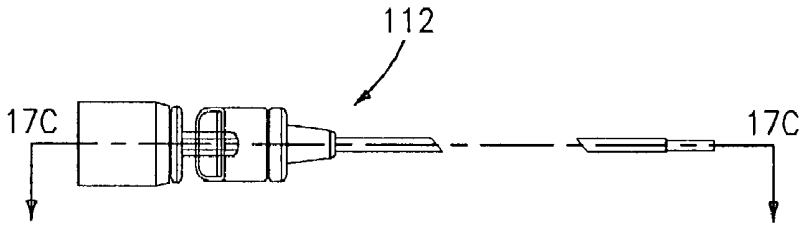

FIG. 17B

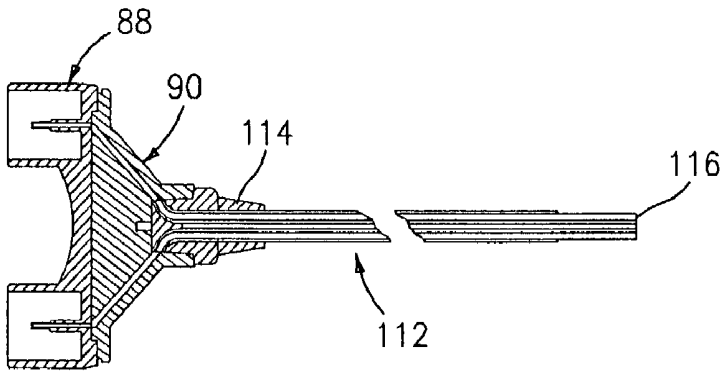

FIG. 17C

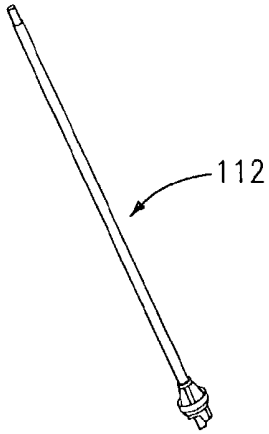

FIG. 18A

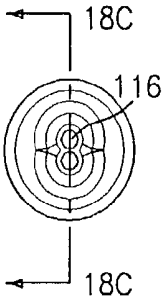

FIG. 18B

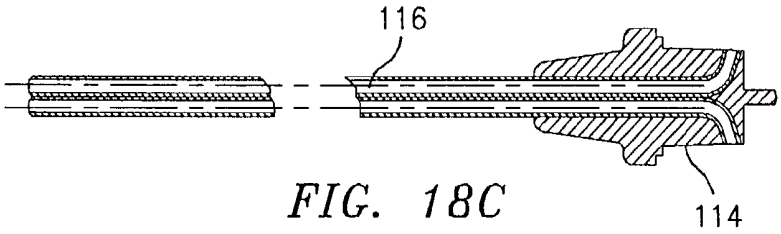

FIG. 18C

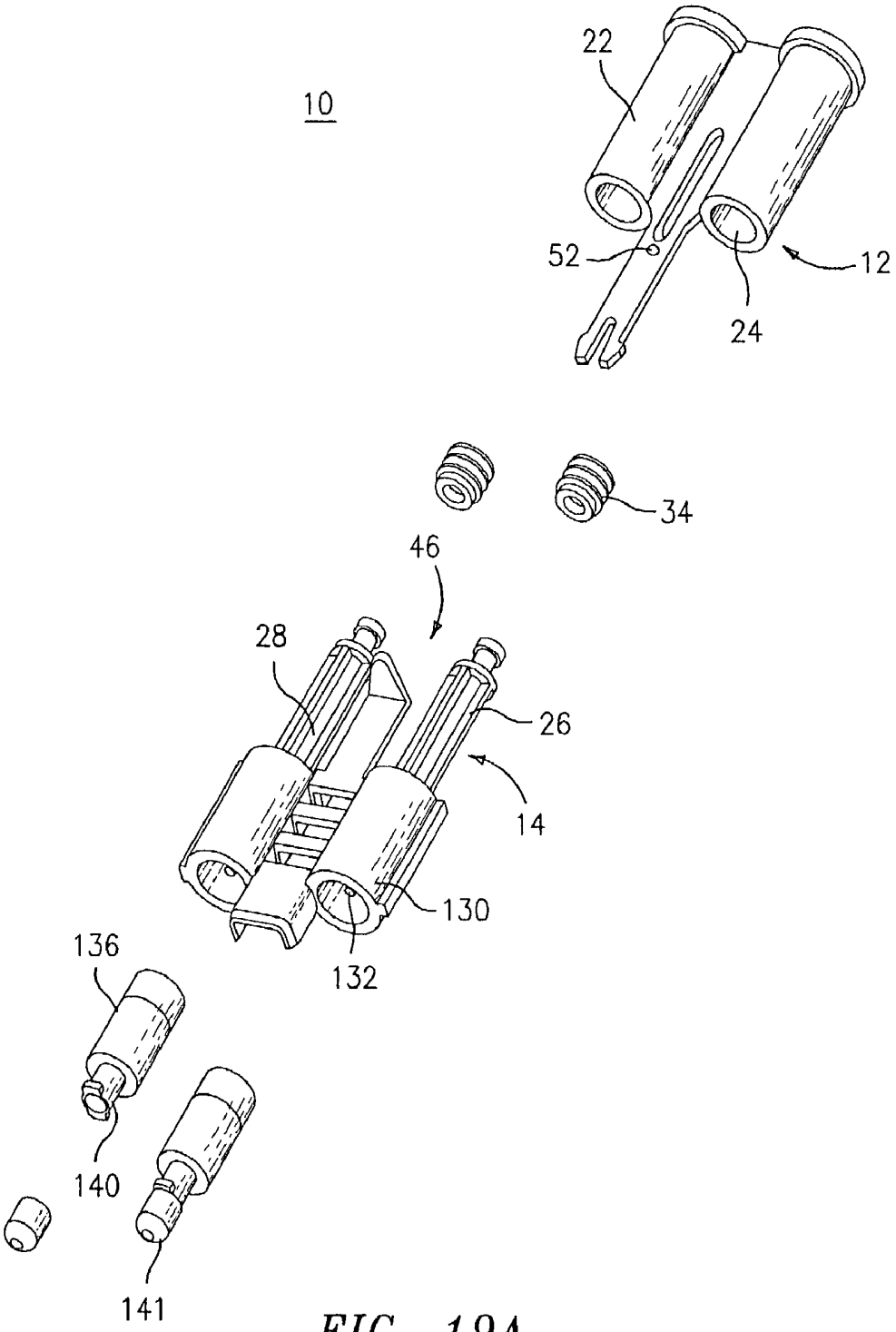

FIG. 19A

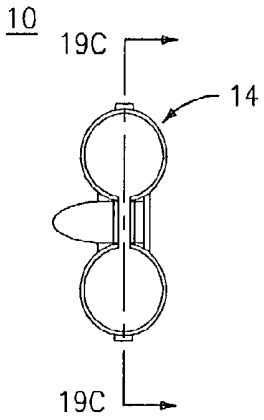

FIG. 19B

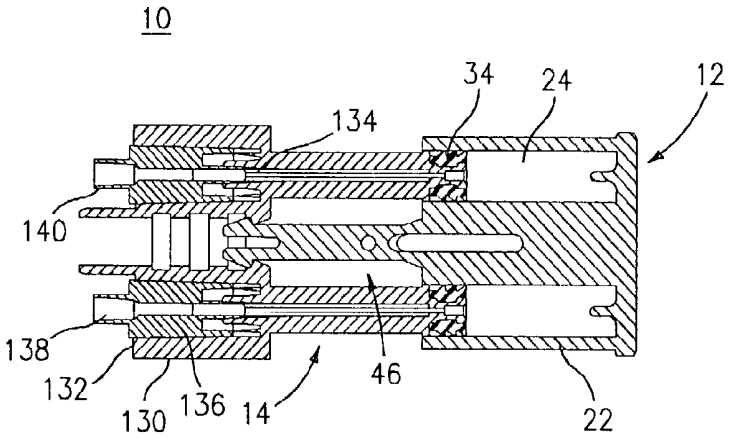

FIG. 19C

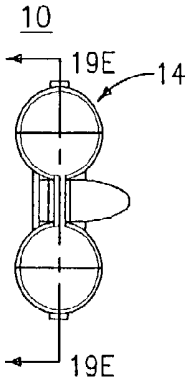

FIG. 19D

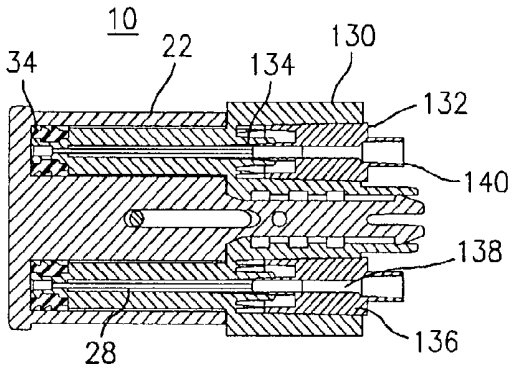

FIG. 19E

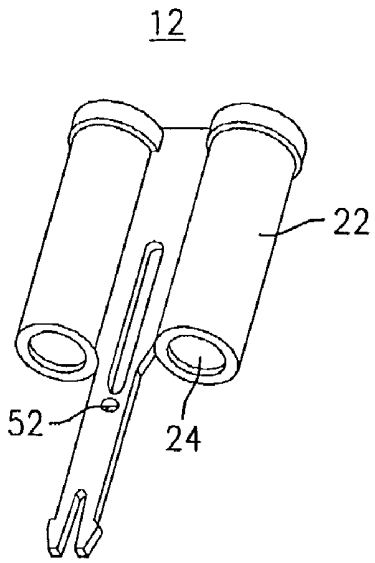

FIG. 20A

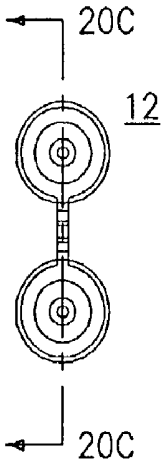

FIG. 20B

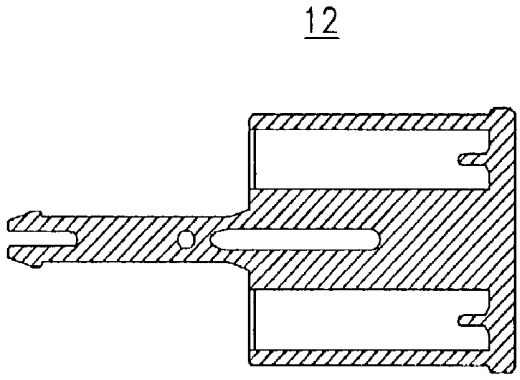

FIG. 20C

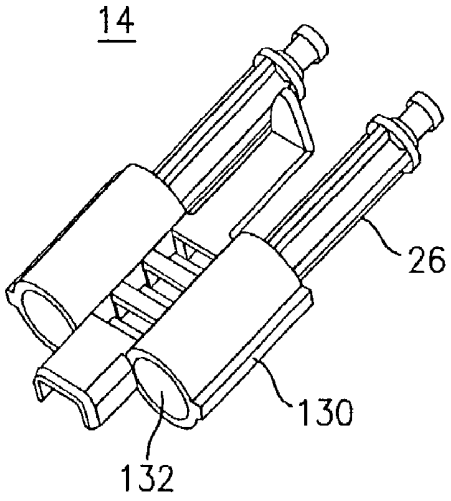

FIG. 21A

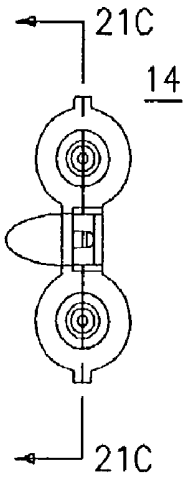

FIG. 21B

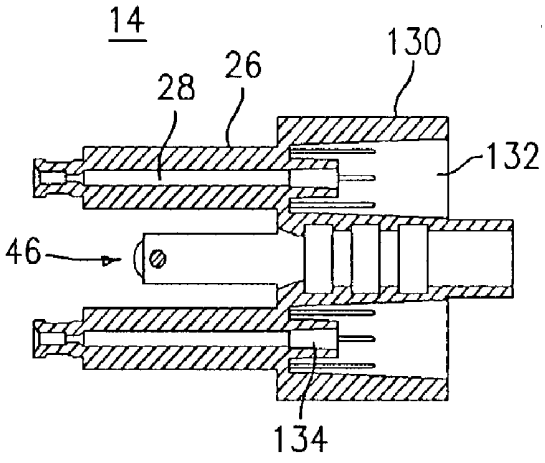

FIG. 21C

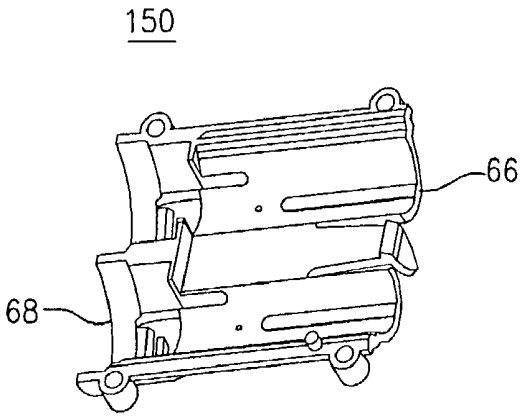

FIG. 22A

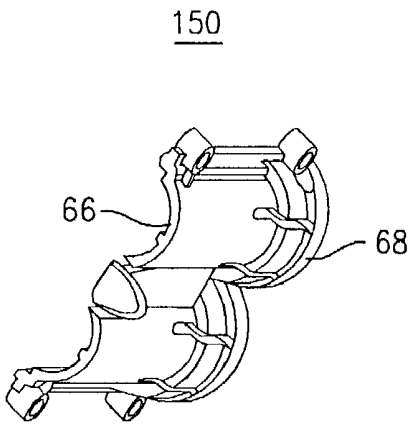

FIG. 22B

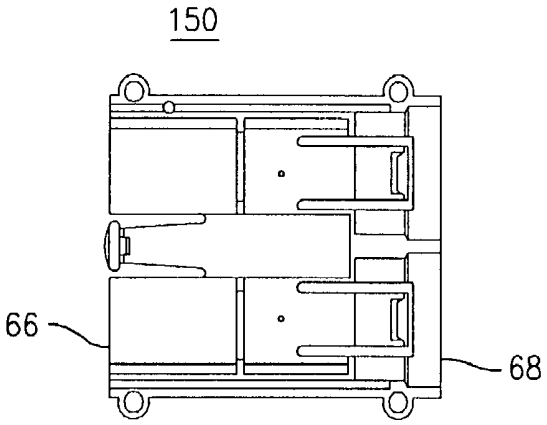

FIG. 22C

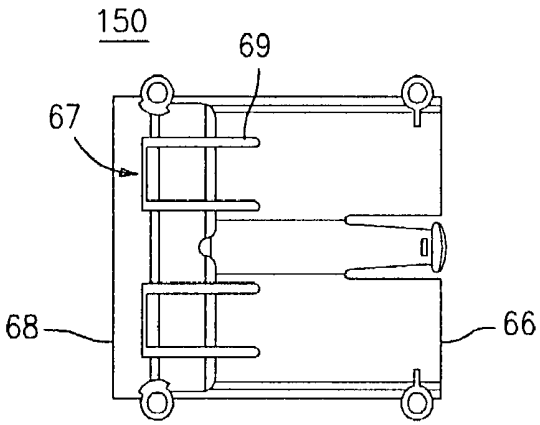

FIG. 22D

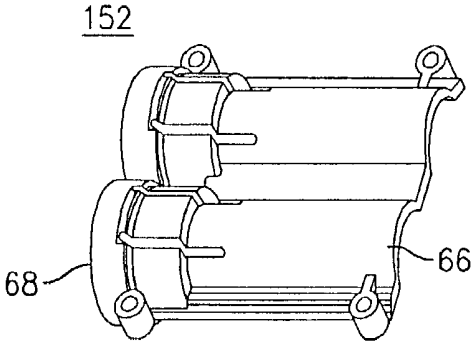

FIG. 23A

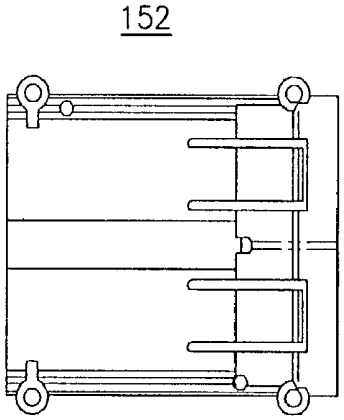

FIG. 23B

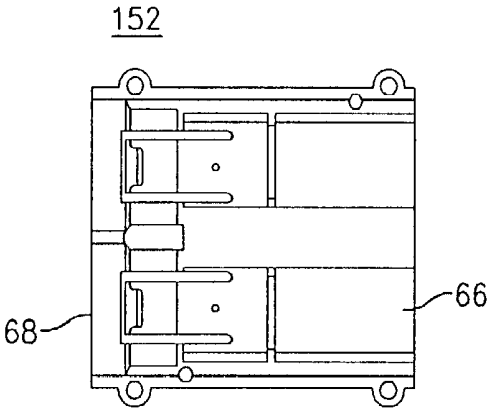

FIG. 23C

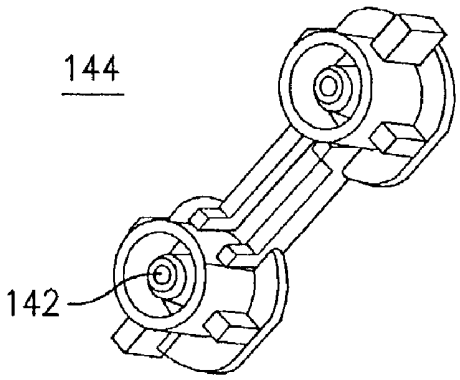

FIG. 24A

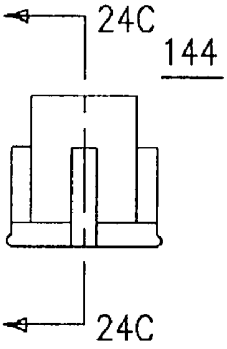

FIG. 24B

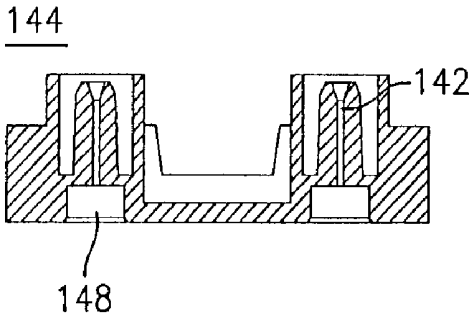

FIG. 24C

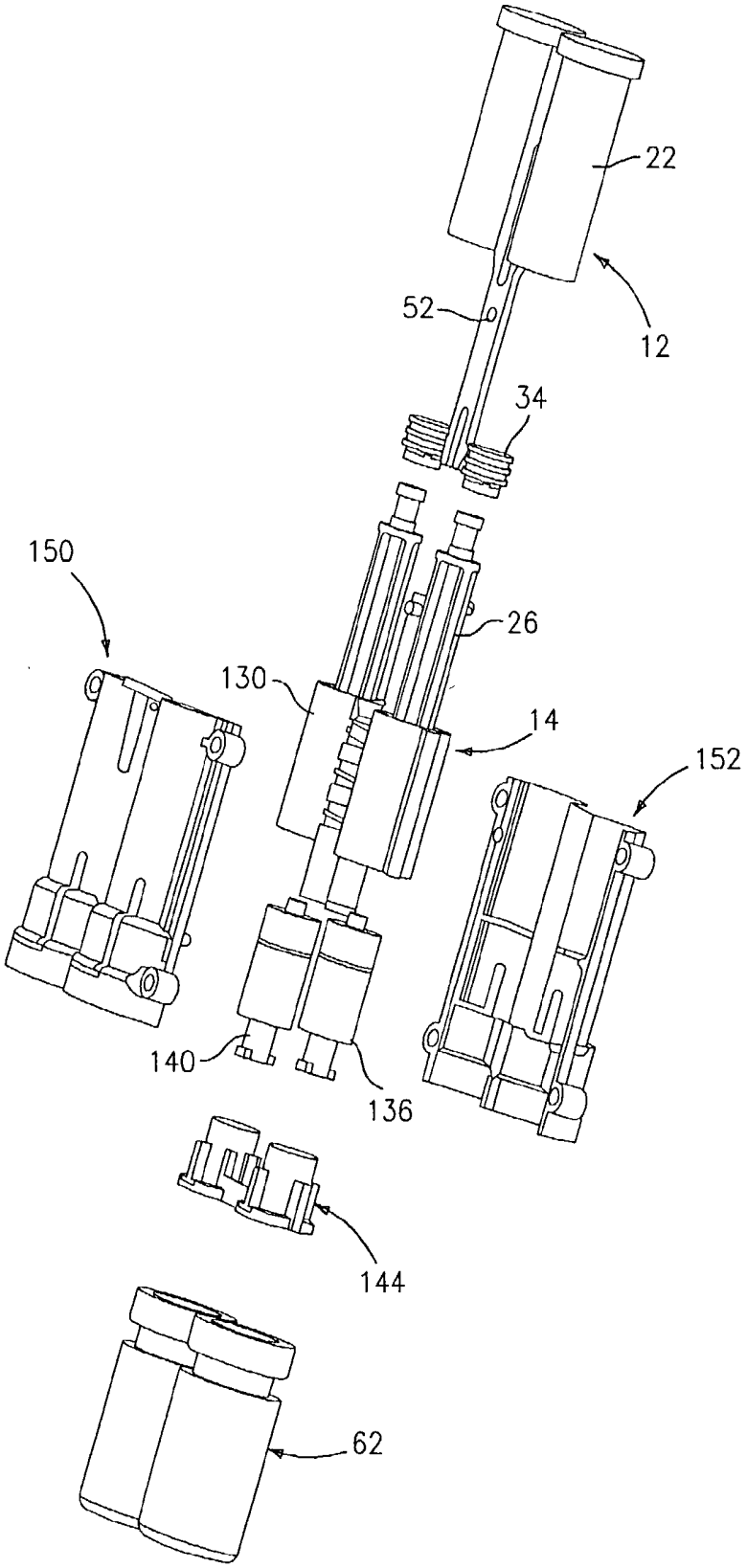

FIG. 25A

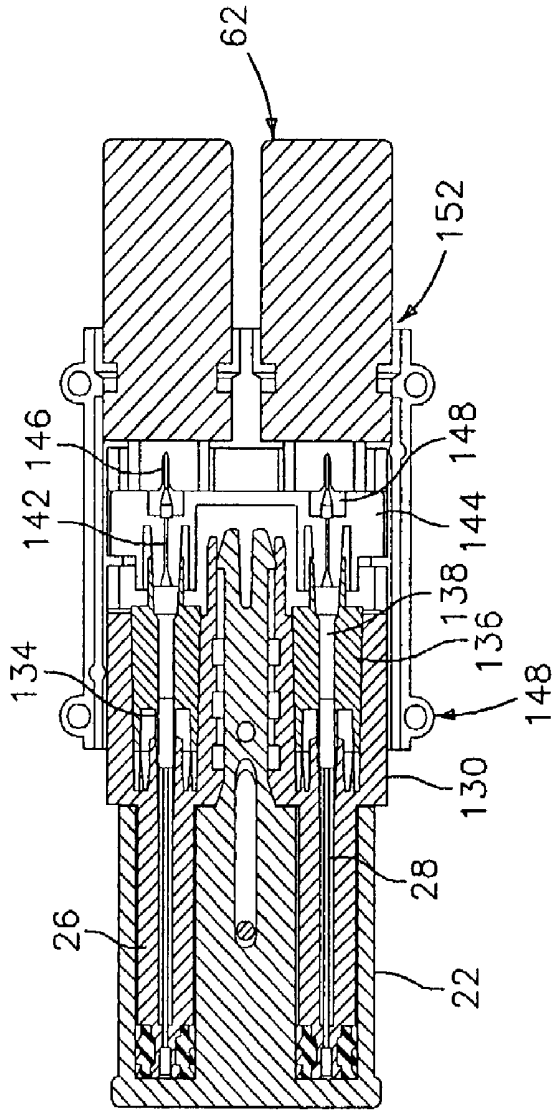

FIG. 25C

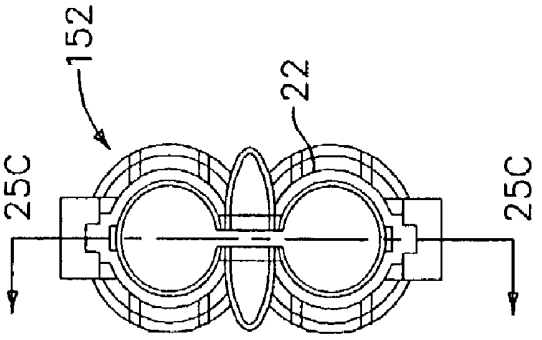

FIG. 25B

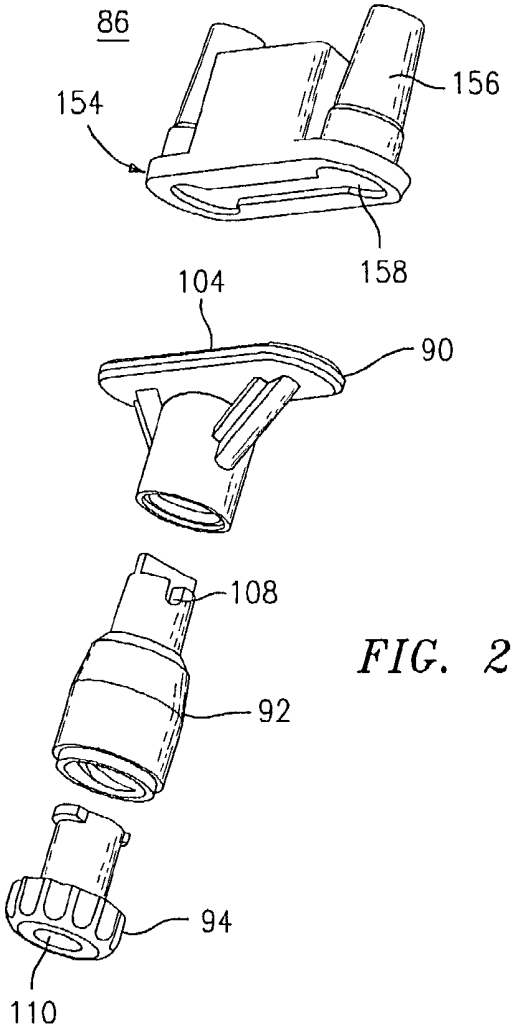

FIG. 26A

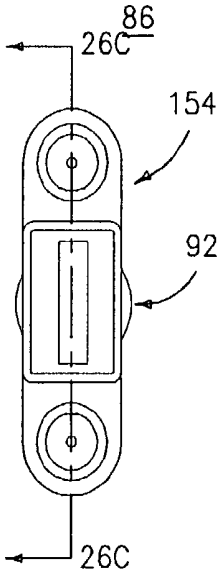

FIG. 26B

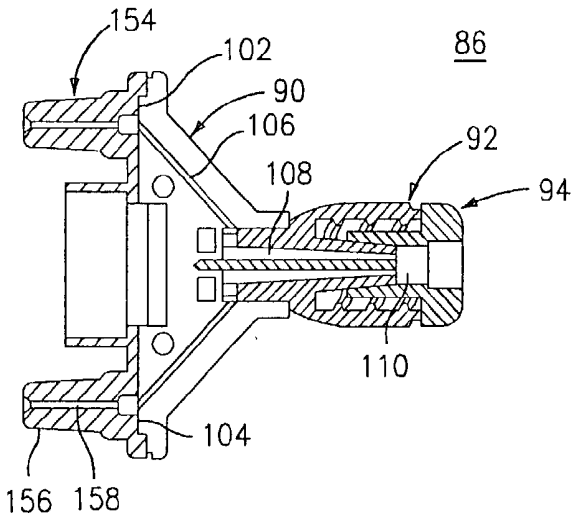

FIG. 26C

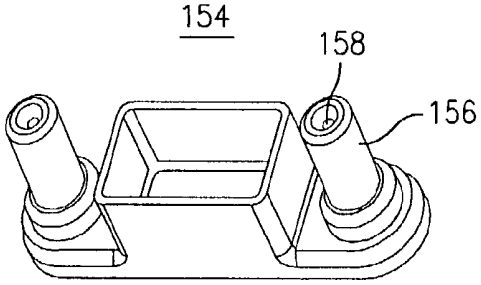

FIG. 27A

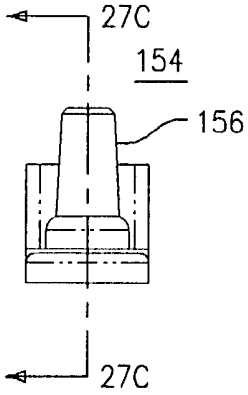

FIG. 27B

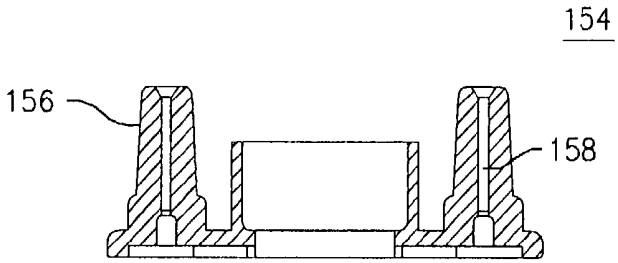

FIG. 27C

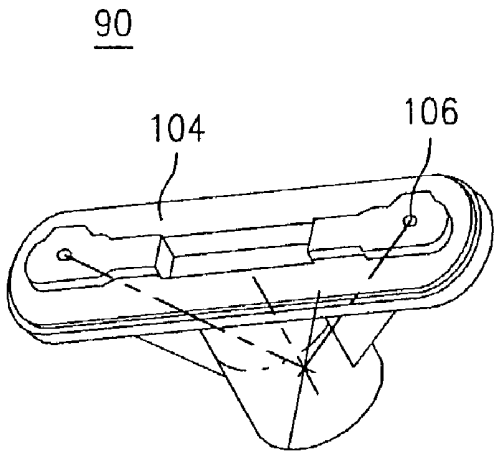

FIG. 28A

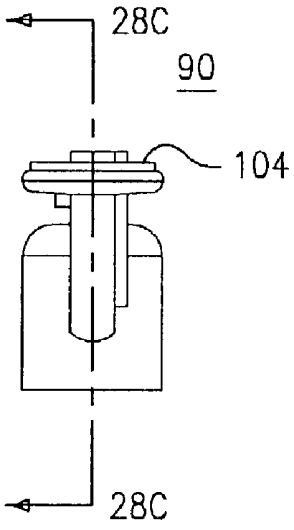

FIG. 28B

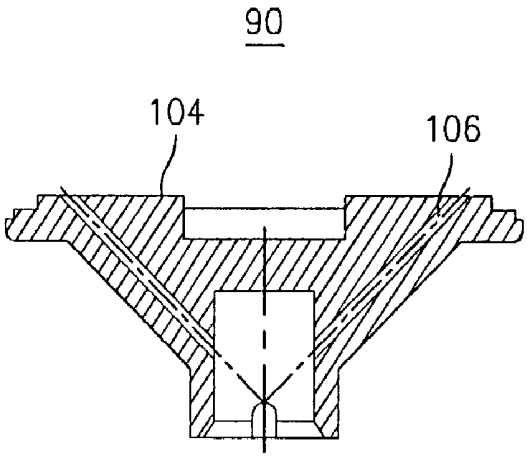

FIG. 28C

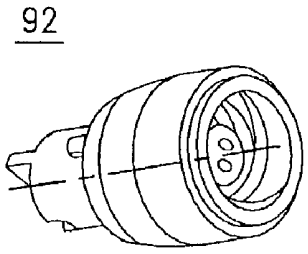

FIG. 29A

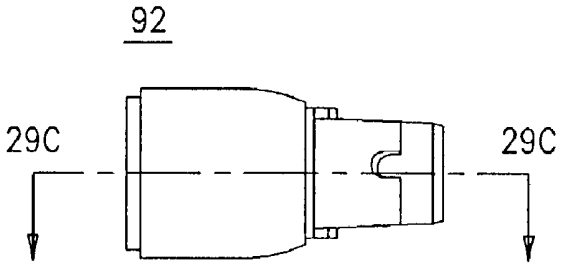

FIG. 29B

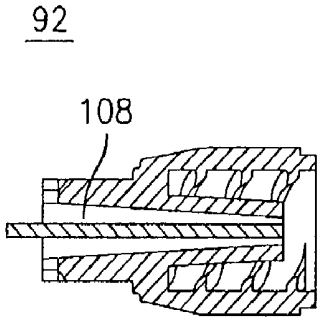

FIG. 29C

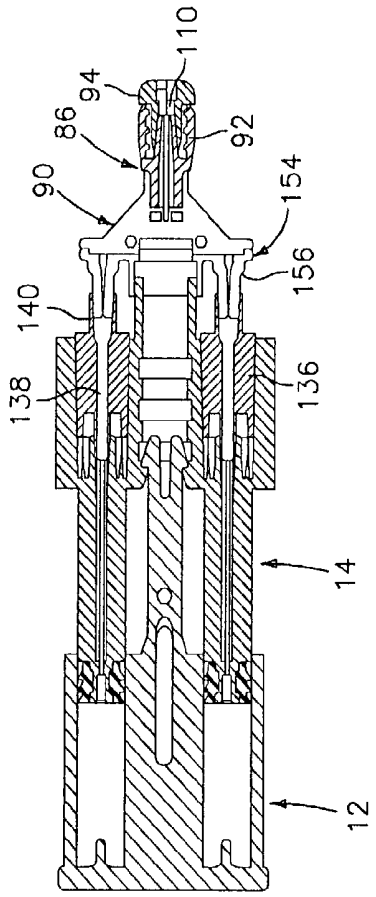

FIG. 30B

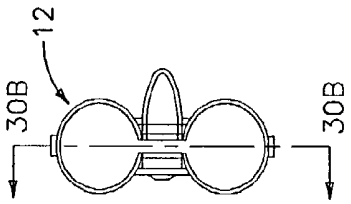

FIG. 30A

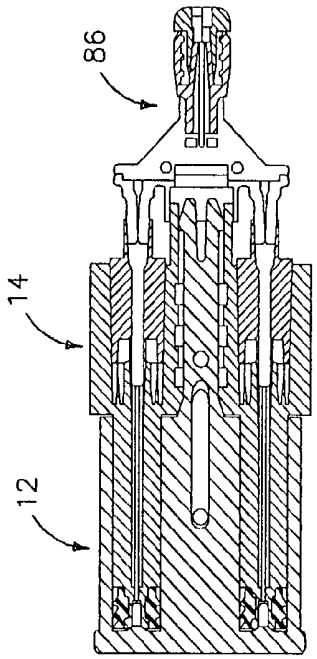

FIG. 30D

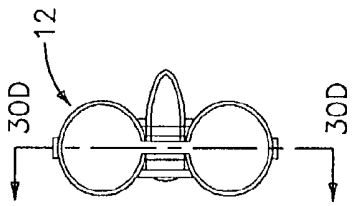

FIG. 30C

FIBRIN SEALANT APPLICATOR SYSTEM

PRIORITY

[0001] This application claims priority to a U.S. provisional application filed on Oct. 5, 1998 and having U.S. Provisional Application Serial No. 60/103,073; the contents of which are incorporated herein by reference.

BACKGROUND

[0002] 1. Technical Field

[0003] The disclosure relates generally to an applicator system for applying a tissue sealant based on human or animal proteins and more particularly to an apparatus for applying an adhesive formed by combining solutions of the proteins to tissues or organs for sealing wounds or leaks, stopping bleeding and the like.

[0004] 2. Description of Related Art

[0005] A fibrin sealant is a biological adhesive sealant formed by mixing two protein components, including fibrinogen and thrombin. Each protein component is derived from human plasma and is subjected to virus elimination and/or inactivation procedures. The components are typically individually dehydrated and stored in separate vials as sterile freeze-dried powders.

[0006] It is known that purified fibrinogen and thrombin, together with a variety of known adjuvants, can be combined in vitro to produce a hemostatic agent and/or a tissue sealant. Because of the rapid 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 delivered by devices such as a dual syringe apparatus.

[0007] 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. Redl et al. disclose 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 onto the application site.

[0008] A dual syringe apparatus for the application of fibrinogen and thrombin solutions to an application site generally contain 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, known fibrin sealant applicators, such as disclosed in U.S. Pat. No. 4,359,049 to Redl et al. discussed above, and in U.S. Pat. No. 4,874,368 to Miller et al. and U.S. Pat. No. 4,979,942 to Wolf et al. are difficult to reuse. The replenishment of the protein components typically require a combination of steps including, inter alia, 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" connector, adding fibrinogen to one syringe and thrombin to another syringe, replacing the syringe plunger, replacing the plunger clip, and dispensing the solutions. In an application where time is of the essence, such a lengthy replenishing process is impractical and cumbersome.

[0009] Therefore, it would be advantageous to provide a fibrin sealant applicator system which obviates the need to replenish the solutions after the solutions have been depleted; provides for a quick and error-proof method of usage; keeps the solutions within air-sealed compartments prior to usage to prevent air from mixing with the solutions; and is economical.

SUMMARY

[0010] Fibrin sealant applicator systems are provided for dispensing a first and a second protein solution to form a biological adhesive which overcome the disadvantages of the prior art. The first and second protein solutions are preferably fibrinogen and thrombin solutions which may intermix on an application site or within the applicator to form a fibrin sealant. The fibrin sealant applicator systems according to the present disclosure include two piston-type sub-assemblies coupled to two vials storing the fibrinogen and thrombin via a coupling unit. The piston-type sub-assemblies store sterilized water within reservoirs which are in fluid communication with the vials via the coupling unit. The water is forced into the vials to form the fibrinogen and thrombin solutions. The solutions are then drawn into the reservoirs and a Y-coupler is attached to the distal end of the piston-type sub-assemblies. The Y-coupler provides fluid communication between the reservoirs and a nozzle body for dispensing the solutions when distal pressure is created within the reservoirs to force the solutions towards the nozzle body.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Various embodiments are described herein with reference to the drawings, wherein:

[0012] FIGS. **1-18** illustrate the components and method of operation of a fibrin sealant applicator in accordance with a first embodiment of the present disclosure wherein:

[0013] **FIG. 1A** is an exploded view of two piston-type sub-assemblies;

[0014] **FIG. 1B** is a top plan view of the two piston-type sub-assemblies shown by **FIG. 1A** in an open configuration;

[0015] **FIG. 1C** is a cross-sectional view of the two piston-type sub-assemblies taken along line A-A in **FIG. 1B**;

[0016] **FIG. 1D** is a top plan view of the two piston-type sub-assemblies shown by **FIG. 1A** in a closed configuration;

[0017] **FIG. 1E** is a cross-sectional view of the two piston-type sub-assemblies taken along line A-A in **FIG. 1D**;

[0018] **FIG. 2A** is a perspective view of two cylindrical reservoirs of the subassemblies shown by FIGS. **1A-1E**;

[0019] **FIG. 2B** is a bottom plan view of the two cylindrical reservoirs shown by **FIG. 2A**;

[0020] **FIG. 2C** is a cross-sectional view of the two cylindrical reservoirs taken along line A-A in **FIG. 2B**;

[0021] **FIG. 3A** is a perspective view of two pistons of the sub-assemblies shown by FIGS. **1A-1E**;

[0022] **FIG. 3B** is a bottom plan view of the two pistons shown by **FIG. 3A**;

[0023] **FIG. 3C** is a cross-sectional view of the two pistons taken along line A-A in **FIG. 3B**;

[0024] **FIG. 4A** is a perspective view of a septum for sealing a distal end of each piston shown by FIGS. **3A-3C**;

[0025] **FIG. 4B** is a top view of the septum shown by **FIG. 4A**;

[0026] **FIG. 5A** is a perspective view of a seal for connection to a proximal end of each piston shown by FIGS. **3A-3C**;

[0027] **FIG. 5B** is a bottom plan view of the seal shown by **FIG. 5A**;

[0028] **FIG. 5C** is a cross-sectional view of the seal shown by **FIG. 5A** taken along line A-A in **FIG. 5B**;

[0029] **FIGS. 6A and 6B** are perspective views of the bottom portion of a loading unit;

[0030] **FIG. 6C** is a top plan view of one side of the bottom portion shown by **FIGS. 6A and 6B**;

[0031] **FIG. 6D** is a top plan view of an opposite side of the bottom portion shown by **FIGS. 6A and 6B**;

[0032] **FIG. 7A** is a perspective view of the top portion of the loading unit;

[0033] **FIG. 7B** is a top plan view of one side of the top portion shown by **FIG. 7A**;

[0034] **FIG. 7C** is a top plan view of an opposite side of the top portion shown by **FIG. 7A**;

[0035] **FIG. 8A** is a perspective view of a hollow needle;

[0036] **FIG. 8B** is a side view of the hollow needle shown by **FIG. 8A**;

[0037] **FIG. 8C** is a cross-sectional view of the hollow needle shown by **FIG. 8A** taken along line A-A in **FIG. 8B**;

[0038] **FIG. 9A** is a perspective view of the hollow needle placed within a shuttle of the loading unit for piercing a seal on a vial inserted within the loading unit;

[0039] **FIG. 9B** is an assembly view of the hollow needle shown by **FIG. 9A** being placed within the shuttle;

[0040] **FIG. 9C** is a side view of the hollow needle-shuttle assembly;

[0041] **FIG. 9D** is a cross-sectional view of the hollow needle-shuttle assembly shown by **FIG. 9C** taken along line A-A in **FIG. 9C**;

[0042] **FIG. 9E** is an enlarged view of the area of detail indicated by arrow "B" in **FIG. 9D**;

[0043] **FIG. 10A** is an assembly view showing coupling of the two piston-type sub-assemblies, the loading unit, and the vials;

[0044] **FIG. 10B** is top plan view of the components shown by **FIG. 10A**;

[0045] **FIG. 10C** is a cross-sectional view of the components shown by **FIG. 10A** taken along line A-A in **FIG. 10B**;

[0046] **FIG. 10D** is a top plan view of the assembled components shown by **FIG. 10A** with the shuttle in a non-piercing position and the piston-type sub-assemblies in the open configuration;

[0047] **FIG. 10E** is a cross-sectional view of the assembled components shown by **FIG. 10D** taken along line A-A in **FIG. 10D**;

[0048] **FIG. 10F** is a top plan view of the assembled components shown by **FIG. 10A** with the shuttle in a piercing position and the piston-type sub-assemblies in the open configuration;

[0049] **FIG. 10G** is a cross-sectional view of the assembled components shown by **FIG. 10F** taken along line A-A in **FIG. 10F**;

[0050] **FIG. 10H** is a top plan view of the assembled components shown by **FIG. 10A** with the shuttle in the piercing position and the piston-type sub-assemblies in the closed configuration;

[0051] **FIG. 10I** is a cross-sectional view of the assembled components shown by **FIG. 10H** taken along line A-A in **FIG. 10H**;

[0052] **FIG. 11A** is an exploded of a Y-coupler;

[0053] **FIG. 11B** is a top plan view of the Y-couple shown by **FIG. 11A**;

[0054] **FIG. 11 C** is a cross-sectional view of the Y-coupler shown by **FIG. 11A** taken along line A-A in **FIG. 11B**;

[0055] **FIG. 11D** is a cross-sectional view of the Y-coupler shown by **FIG. 11A** taken along line C-C in **FIG. 11C**;

[0056] **FIG. 12A** is a perspective view of an adaptor of the Y-coupler shown by **FIG. 11A**;

[0057] **FIG. 12B** is a side view of the adaptor shown by **FIG. 12A**;

[0058] **FIG. 12C** is a cross-sectional view of the adaptor shown by **FIG. 12A** taken along line A-A in **FIG. 12B**;

[0059] **FIG. 13A** is a perspective view of a body tip of the Y-coupler shown by **FIG. 11A**;

[0060] **FIG. 13B** is a side view of the body tip shown by **FIG. 13A**;

[0061] **FIG. 13C** is a cross-sectional view of the body tip shown by **FIG. 13A** taken along line A-A in **FIG. 13B**;

[0062] **FIG. 14A** is a perspective view of a collar of the Y-coupler shown by **FIG. 11**;

[0063] **FIG. 14B** is a side view of the collar shown by **FIG. 14A**;

[0064] **FIG. 14C** is a cross-sectional view of the collar shown by **FIG. 14A** taken along line A-A in **FIG. 14B**;

[0065] **FIG. 15A** is a perspective view of a nozzle body of the Y-coupler shown by **FIG. 11A**;

[0066] **FIG. 15B** is a top plan view of the nozzle body shown by **FIG. 15A**;

[0067] **FIG. 16A** is an assembly view of coupling the two piston-type sub-assemblies and the Y-coupler;

[0068] **FIG. 16B** is a top plan view of the assembled components shown by **FIG. 16A** with the piston-type sub-assemblies in the open configuration;

[0069] **FIG. 16C** is a cross-sectional view of the assembled components shown by **FIG. 16B** taken along line A-A in **FIG. 16B**;

[0070] **FIG. 16D** is a top plan view of the assembled components shown by **FIG. 16A** with the piston-type sub-assemblies in the closed configuration;

[0071] **FIG. 16E** is a cross-sectional view of the assembled components shown by **FIG. 16D** taken along line A-A in **FIG. 16D**;

[0072] **FIG. 17A** is a perspective view of the components of a laparoscopic tip assembly configured for coupling to the two piston-type sub-assemblies shown by **FIG. 11A**;

[0073] **FIG. 17B** is a side view of the assembled components of the laparoscopic tip assembly shown by **FIG. 17A**;

[0074] **FIG. 17C** is a cross-sectional view of the assembled components shown by **FIG. 17B** taken along line A-A in **FIG. 17B**;

[0075] **FIG. 18A** is a perspective view of the laparoscopic tip shown by **FIG. 17A**;

[0076] **FIG. 18B** is a top plan view of the laparoscopic tip shown by **FIG. 18A**;

[0077] **FIG. 18C** is a cross-sectional view of the laparoscopic tip shown by **FIG. 18A** taken along line A-A in **FIG. 18B**;

[0078] FIGS. **19-30** illustrate the components and method of operation of a fibrin sealant applicator in accordance with a second embodiment of the present disclosure wherein:

[0079] **FIG. 19A** is an exploded is an exploded view of two piston-type sub-assemblies;

[0080] **FIG. 19B** is a top plan view of the two piston-type sub-assemblies shown by **FIG. 19A** in an open configuration;

[0081] **FIG. 19C** is a cross-sectional view of the two piston-type sub-assemblies taken along line A-A in **FIG. 19B**;

[0082] **FIG. 19D** is a top plan view of the two piston-type sub-assemblies shown by **FIG. 19A** in a closed configuration;

[0083] **FIG. 19E** is a cross-sectional view of the two piston-type sub-assemblies taken along line A-A in **FIG. 19D**;

[0084] **FIG. 20A** is a perspective view of two cylindrical reservoirs of the sub-assemblies shown by FIGS. **19A-19E**;

[0085] **FIG. 20B** is a bottom plan view of the two cylindrical reservoirs shown by **FIG. 20A**;

[0086] **FIG. 20C** is a cross-sectional view of the two cylindrical reservoirs taken along line A-A in **FIG. 20B**;

[0087] **FIG. 21A** is a perspective view of two pistons of the sub-assemblies shown by FIGS. **19A-19E**;

[0088] **FIG. 21B** is a bottom plan view of the two pistons shown by **FIG. 21A**;

[0089] **FIG. 21C** is a cross-sectional view of the two pistons taken along line AA in **FIG. 21B**;

[0090] **FIGS. 22A and 22B** are perspective views of the bottom portion of a loading unit;

[0091] **FIG. 22C** is a top plan view of one side of the bottom portion shown by **FIGS. 22A and 22B**;

[0092] **FIG. 22D** is a top plan view of an opposite side of the bottom portion shown by **FIGS. 22A and 22B**;

[0093] **FIG. 23A** is a perspective view of the top portion of the loading unit;

[0094] **FIG. 23B** is a top plan view of one side of the top portion shown by **FIG. 23A**;

[0095] **FIG. 23C** is a top plan view of an opposite side of the top portion shown by **FIG. 23A**;

[0096] **FIG. 24A** is a perspective view of an adaptor for connecting check-valves to vials;

[0097] **FIG. 24B** is a side view of the adaptor shown by **FIG. 24A**;

[0098] **FIG. 24C** is a cross-sectional view of the adaptor shown by **FIG. 24A** taken along line A-A in **FIG. 24B**;

[0099] **FIG. 250A** is an assembly view showing coupling of the two piston-type sub-assemblies, the check-valves, the adaptor, and the vials;

[0100] **FIG. 25B** is top plan view of the assembled components shown by **FIG. 25A**;

[0101] **FIG. 25C** is a cross-sectional view of the assembled components shown by **FIG. 25B** taken along line A-A in **FIG. 25B**;

[0102] **FIG. 26A** is an exploded of a Y-coupler;

[0103] **FIG. 26B** is a top plan view of the Y-couple shown by **FIG. 26A**;

[0104] **FIG. 26C** is a cross-sectional view of the Y-coupler shown by **FIG. 26A** taken along line A-A in **FIG. 26B**;

[0105] **FIG. 27A** is a perspective view of an adaptor of the Y-coupler shown by **FIG. 26A**;

[0106] **FIG. 27B** is a side view of the adaptor shown by **FIG. 27A**;

[0107] **FIG. 27C** is a cross-sectional view of the adaptor shown by **FIG. 27A** taken along line A-A in **FIG. 27B**;

[0108] **FIG. 28A** is a perspective view of a body tip of the Y-coupler shown by **FIG. 27A**;

[0109] **FIG. 28B** is a side view of the body tip shown by **FIG. 28A**;

[0110] **FIG. 28C** is a cross-sectional view of the body tip shown by **FIG. 28A** taken along line A-A in **FIG. 28B**;

[0111] **FIG. 29A** is a perspective view of a collar of the Y-coupler shown by **FIG. 27A**;

[0112] **FIG. 29B** is a side view of the collar shown by **FIG. 29A**;

[0113] **FIG. 29C** is a cross-sectional view of the collar shown by **FIG. 29A** taken along line A-A in **FIG. 29B**;

[0114] **FIG. 30A** is a top plan view of the piston-type sub-assemblies in the open configuration coupled to the Y-coupler;

[0115] **FIG. 30B** is a cross-sectional view of the assembled components shown by **FIG. 30A** taken along line A-A in **FIG. 30A**;

[0116] **FIG. 30C** is a top plan view of the piston-type sub-assemblies in the closed configuration coupled to the Y-coupler; and

[0117] **FIG. 30D** is a cross-sectional view of the assembled components shown by **FIG. 30C** taken along line A-A in **FIG. 30C**.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0118] Two embodiments of a fibrin sealant applicator system are described herein below in conjunction with FIGS. **1A-30D**. With reference to FIGS. **1A-18C**, the components and method of operation of the first embodiment of the fibrin sealant applicator system are described. With reference to FIGS. **19A-30D**, the components and method of operation of the second embodiment of the fibrin sealant applicator system are described. The fibrin sealant applicator system embodiments described herein below are preferably manufactured from biodegradable plastics and other materials. In their preferred embodiments, both are packaged as a kit and used only once to apply a solution of fibrinogen and a solution of thrombin to an application site.

[0119] Referring to FIGS. **1-10**, the components used during the formation and loading of the fibrinogen and thrombin solutions to the first embodiment of the fibrin sealant applicator system will now be described. For this purpose, the fibrin sealant applicator system includes two piston-type sub-assemblies **10** (FIGS. **1A-1E**) coupled together and each having a reservoir assembly **12** (FIGS. **2A-2C**), a piston assembly **14** (FIGS. **3A-3C**), a septum **16** (FIGS. **4A-4B**); and a coupling unit **18** (FIGS. **6A-6D** and **7A-7C**) having two hollow needles **20** (FIGS. **8A-8C** and **9A-9E**) therein.

[0120] Each reservoir assembly **12** includes a cylindrical reservoir **22** having a compartment **24** for storing sterilized water therein. The sterilized water is preferably stored within compartment **24** of each reservoir **22** during manufacturing and hermetically sealed therein to prevent contamination thereof. Each reservoir assembly **12** is preferably made from polypropylene.

[0121] Each piston assembly **14** includes a piston **26** having a bore **28** therethrough (FIGS. **3A-3C**), an elongated cylindrical tube **30** extending through bore **28**, a distal seal **32**, and a proximal seal **34**. Each piston assembly **14** is preferably made from polypropylene and distal and proximal seals **32** and **34** are preferably made from silicone. Distal seal **32**, as shown by FIGS. **4A-4B**, is semi-spherical in shape and configured to matingly engage seal **16**. Distal seal **32**.and seal **16** are then attached to the distal end of piston assembly **14** as shown by **FIG. 1A** to prevent contaminants from entering the two piston-type sub-assemblies **10**.

[0122] Proximal seal **34**, as. shown by FIGS. **5A-5C**, is cylindrical in shape having a bore **36** therethrough and threads **38** on an inner and outer surface. Proximal seal **34** is configured for placement on a proximal end of piston assembly **14** to wedge the proximal end of piston **26** within compartments **24** as shown by **FIG. 1A**. Distal and proximal seals **32** and **34** prevent contaminants from entering the piston-type subassemblies and compromising the sterility of the sterile water within compartment **24** of each reservoir **22**.

[0123] A connecting mechanism **40** connects each piston assembly **14**. Connecting mechanism **42** includes a hatch-bar **44** having a finger-controlled locking assembly **46**. Locking assembly **46** includes a rest bar **48** having tab **50** protruding therefrom. Rest bar **48** moves from an unlocked position to a locked position to move tab **50** to matingly engage a hole **52** (**FIGS. 1A and 2A**) on reservoir assembly **12** to lock reservoir assembly **12** to piston assembly **14**. This prevents reservoirs **22** from being inadvertently moved distally or pushed against pistons **26**. When the solutions are ready to be dispensed, the operator can use a finger to lift rest bar **48** to disengage tab **50** from within hole **52**. Accordingly, locking assembly **46** is unlocked, thereby allowing free movement of reservoir assembly **12** along the longitudinal axis of piston assembly **14**. It is contemplated to design locking assembly **46** to also provide a locking function when reservoir assembly **12** has been moved distally towards piston assembly **14** to prevent proximal movement of reservoir assembly **12**.

[0124] With reference to **FIGS. 1C, 1E** and **10A-10I**, each reservoir **22** is in fluid communication with the distal end of corresponding piston **26** via bore **54** extending within tube **30**. It is contemplated to size bore **54** to allow for little or no water to remain therein when dispensing the sterilized water to vials containing powdered fibrinogen and thrombin, as further described below.

[0125] A coupling unit **56** (FIGS. **6A-6D** and **7A-7C**) having body half portions **58** and **60** acts as an interface between piston-type sub-assemblies **10** and vials **62** (See FIGS. **10A-10I**). Coupling unit **56** includes molded compartments therein for fitting vials **62** and a shuttle **64**. Coupling unit **56** includes a proximal interface **66** for receiving and coupling to the two piston-type sub-assemblies **10** and a distal interface **68** for receiving and coupling to vials **62** storing fibrinogen and thrombin. Vials **62** are inserted within distal interface **68** and are coupled to the coupling unit by a coupling mechanism **67**. Coupling mechanism **67** includes flexible tabs **69** which flex outwardly as vials **62** are inserted within distal interface **68** and then flex back to grip the neck of vials **62** and hold them in place. Body half portions **58** and **60** of the coupling unit **56** are preferably made from ABS plastics.

[0126] With reference to FIGS. **9A-9E**, shuttle **64** includes two proximal hollow needles **70** within recess **72** for piercing septum **16** and distal seal **32** when the two piston-type sub-assemblies **10** are inserted within proximal interface **66**. Recess **72** is configured to matingly engage the distal end of pistons **26** and to securely connect coupling unit **56** with the two piston-type sub-assemblies **10**. The distal hollow needles **74** (FIGS. **8A-8C** and **9A-9E**) having a base **76** are matingly engaged to distal recesses **78** on shuttle **64** (FIGS. **10A-10I**) for piercing a seal overlaying vials **62**. Proximal hollow needles **70**, distal hollow needles **74**, and bores **80** within shuttle **64** form passageways **82** for providing fluid

communication between the distal end of piston assembly **14** and vials **62** as shown by **FIGS. 9D, 9E, 10**C, **10**E, **10**G and **10**I.

[**0127**] Shuttle **64** is capable of moving between tabs **84** within coupling unit **56** and hatch-bar **44** of the piston assembly **14**. Therefore, in order to prevent inadvertent piercing of the seal overlaying vials **62**, shuttle **64** is kept positioned near proximal interface **66** of coupling unit **56** until the operator is ready to form the solutions.

[**0128**] With reference to FIGS. **10**D-**10**I, the solutions are formed by moving shuttle **64** distally from a non-piercing position to a piercing position in order for needles **74** to pierce the seal overlaying vials **62** (**FIG. 10G**). Distal holding needles **74** are preferably made from nylon. Reservoir assembly **12** is then moved distally to decrease the volumetric capacity within compartments **24** to force the sterilized water therein to flow distally through bores **54** of tubes **30** (**FIG. 10I**). The water flows through bores **54** and passageways **82** into vials **62**. The entire assembly is then shaken to thoroughly mix the water with the powdered fibrinogen and thrombin to form the solutions. Reservoir assembly **12** is then moved proximally away from piston assembly **14** creating proximal pressure within the reservoirs **22** to draw the solutions from vials **62** to reservoirs **22**.

[**0129**] When the solutions have been drawn into reservoirs **22**, shuttle **64** is moved proximally to remove needles **74** from within vials **62**. Vials **62** are then removed from distal interface **68** of coupling unit **56**. Coupling unit **56** is subsequently removed from the two piston-type sub-assemblies **10** and a Y-coupler unit **86** (FIGS. **11**A-**11**D) is then coupled to the two piston-type sub-assemblies **10** as shown by FIGS. **16**A-**16**E.

[**0130**] Y-coupler unit **86** includes an adaptor **88**, a body tip **90**, a collar **92**, a nozzle body **94**, and a seal **96**. The components are assembled together as shown by FIGS. **11**A-**11**D to form Y-coupler **86**. Adaptor **88** includes two hollow needles **98** recessed within cavities **100** to prevent accidental piercing or pricking of an operator's finger (FIGS. **12**A-**12**C). Hollow needles **98** matingly engage seal **16** and distal seal **32** at the distal end of piston assembly **14** to provide fluid communication between reservoirs **22** and distal face **102** of adaptor **88**. Adaptor **88** and body tip **90** are preferably made from polypropylene. Alternatively, adaptor **88** and body tip **90** are made from ABS plastics. Collar **92** and nozzle body **94** are preferably made from ABS plastics.

[**0131**] Distal face **102** connects to proximal face **104** by snap-fitting distal face **102** into proximal face **104** of body tip **90** such that fluid communication is provided between hollow needles **98** and passageways **106** extending within body tip **90** (FIGS. **13**A-**13**C). Passageways **106** lead to cavities **108** within collar **92** (FIGS. **14**A-**14**C). Cavities **108** lead to openings **110** within nozzle body **94** (FIGS. **15**A-**15**B) to dispense any solutions flowing through cavities **108** when seal **96** is absent. Specifically, the solutions are dispensed by moving reservoirs **22** distally to decrease the volumetric capacity therein and force the solutions distally towards openings **110**.

[**0132**] With reference to FIGS. **17**A-**17**C and **18**A-**18**C, a laparoscopic tip **112** having an adaptor **114** for matingly engaging body tip **90** may be provided to the fibrin sealant applicator to provide fluid communication between passageways **106** and bores **116**. It is contemplated that adaptor **88**, body tip **90**, and laparoscopic tip **112** are ultrasonically welded.

[**0133**] Reference will now be made to a second embodiment of the fibrin sealant applicator system in conjunction with FIGS. **19**A-**30**D. The second embodiment works substantially the same as the first embodiment described above and identical reference numerals identify the same or similar components.

[**0134**] The second embodiment includes two piston-type sub-assemblies **10** each having a reservoir assembly **12** (FIGS. **20**A-**20**C) and a piston assembly **14** (FIGS. **21**A-**21**C). Piston assembly **14** includes two check-valve retainers **130** each having a compartment **132** therein. Each compartment **132** includes passageway **134** in fluid communication with bore **28**. A check-valve **136** is placed within each check-valve retainer **130** having a bore **138** therethrough and a nozzle **140** covered by a seal **141** as shown by FIGS. **19**A-**19**E. Each bore **138** is in fluid communication with a corresponding passageway **134** and each nozzle **140** is in fluid communication with a bore **142** within adaptor **144** (FIGS. **24**A-**24**C) as shown by FIGS. **25**A-**25**C. It is contemplated to provide each check-valve **136** with a valve for opening and closing bore **138** traversing therethrough to prevent and allow fluid communication between reservoir assembly **12** and the distal ends of check-valves **136**.

[**0135**] With continued reference to FIGS. **25**A-**25**C, each bore **142** is in fluid communication with a hollow distal needle **146** fitted within a recess **148** of adaptor **144**. Hollow distal needles **146** provide fluid communication between reservoirs **22** and vials **62** when adaptor **144** is moved distally within coupling unit **148** and needles **146** contact and pierce a seal overlaying vials **62**. Coupling unit **148** is similar in design and operation as coupling unit **56** with slight design modifications in top portion **150** (FIGS. **22**A-**22**D) and bottom portion **152** (FIGS. **23**A-**23**C) for housing check-valve retainers **130** and adaptor **144** therein.

[**0136**] Y-coupler **86** (FIGS. **26**A-**26**C) having adaptor **154** (FIGS. **27**A-**27**C), body tip **90** (FIGS. **28**A-**28**C), collar **92** (FIGS. **29**A-**29**C) and nozzle body **94** (see FIGS. **15**A-**15**B of the first embodiment) is fitted to check-valves **136** when vials **62**, adaptor **144** and coupling unit **148** are removed from the two piston-type subassemblies **10** when the solutions have been formed and drawn into reservoirs **22** as shown by FIGS. **30**A-**30**D.

[**0137**] Specifically, with reference to FIGS. **27**A-**27**C, adaptor **154** of Y-coupler **86** includes two male connectors **156** having a bore **158** therein for matingly engaging nozzles **140** of check-valves **136** for providing fluid communication between reservoirs **22** and openings **110** within nozzle body **94**. With reference to FIGS. **30**A-**30**D, the solutions can then be dispensed by distally moving reservoirs **22** to decrease the volumetric capacity therein as discussed above with respect to the first embodiment.

[**0138**] It is contemplated that a laparoscopic tip can also be provided for the second embodiment. It is further contemplated to coat the passageways and bores wherein the solutions flow with a non-stick polymer to prevent the solutions from attaching to the components of the fibrin sealant applicator and to allow the components to be readily cleaned. It is further contemplated that similar components

of the two embodiments are manufactured from the same materials. Additionally, it is further contemplated to provide the components of the two embodiments as a kit. Therefore, it is understood that various modifications may be made to the embodiments disclosed herein.

[0139] Also, besides applying a fibrin sealant, the fibrin sealant applicator systems can be used to perform human or veterinary surgical procedures, such as applying antiseptics and medication. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the above disclosure and appended claims.

What is claimed is:

1. An applicator system for dispensing a first solution and a second solution of a multicomponent biological adhesive, the applicator system comprising:

a piston-reservoir assembly having a reservoir sub-assembly coupled to a piston sub-assembly, said reservoir sub-assembly having two reservoirs and said piston sub-assembly having two pistons, each of said two reservoirs matingly engaging a corresponding one of said two pistons, said two pistons having fluid communication means for communicating fluid from said two reservoirs to a distal end of each of said two pistons; and

a loading unit assembly configured for being coupled with said piston-reservoir assembly and at least two vials each storing at least one component of said multicomponent biological adhesive, said loading unit assembly having movable piercing means for moving towards said at least two vials and piercing a seal on each of said at least two vials, said loading unit assembly further having fluid communication means for communicating fluid from said distal end of each of said two pistons to an interior of each of said at least two vials by distally moving each of said two reservoirs toward each of said two pistons to decrease a volumetric capacity of each of said two reservoirs;

wherein each of said at least one component of said multicomponent biological adhesive is mixed with said fluid communicated from said distal end of each of said two pistons to said interior of each of said at least two vials to form said first and second solutions, said first and second solutions being communicated to a corresponding one of said two reservoirs via said fluid communication means of said loading unit assembly and said fluid communication means of said piston-reservoir assembly by proximally moving each of said two reservoirs toward each of said two pistons to increase said volumetric capacity of each of said two reservoirs, wherein said loading unit assembly being uncoupled from said piston-reservoir assembly for dispensing said first and second solutions of said multicomponent biological adhesive by compressing each of said two reservoirs toward each of said two pistons to decrease said volumetric capacity of each of said two reservoirs.

2. The applicator system according to claim 1, further comprising a dispensing unit assembly having at least two conduits and being configured for being coupled to said piston-reservoir assembly to align said at least two conduits with said fluid communication means of said two pistons.

3. The applicator system according to claim 2, wherein said dispensing unit assembly includes piercing means for piercing a seal fitted on each of said distal ends of said two pistons.

4. The applicator system according to claim 2, wherein said dispensing unit assembly is configured for performing laparoscopic surgical procedures.

5. The applicator system according to claim 3, wherein said piercing means includes two needles having a bore therethrough, said bore of each of said two needles being in fluid communication with said at least two conduits.

6. The applicator system according to claim 1, further comprising locking means for locking said reservoir sub-assembly to said piston sub-assembly to prevent distal movement of said two reservoirs towards said two pistons.

7. The applicator system according to claim 6, wherein said locking means includes a tab protruding from a rest bar of said piston sub-assembly, said tab being dimensioned to matingly engage a hole of said reservoir sub-assembly upon movement of said rest bar from a unlocked position to a locked position.

8. The applicator system of claim 1, further comprising a check-valve assembly having at least two check-valves configured for fitting at each of said distal ends of said two pistons, each of said at least two check-valves having a bore therethrough for providing fluid communication between said fluid communication means of said two pistons and said fluid communication means of said loading unit assembly.

9. The applicator system of claim 8, wherein each of said at least two check-valves includes a valve for preventing fluid communication between said fluid communication means of said two pistons and said fluid communication means of said loading unit assembly via each of said bores of said at least two check-valves.

10. The applicator system of claim 8, further comprising a dispensing unit assembly having at least two conduits and being configured for being coupled to said at least two check-valves to align said at least two conduits with a corresponding one of said two bores of said at least two check-valves.

11. The applicator system according to claim 1, wherein one of said at least two components is thrombin and another of said at least two components is fibrinogen.

12. The applicator system according to claim 11, wherein sterile water is communicated from said two reservoirs to said interior of each of said at least two vials to mix said sterile water with said thrombin and fibrinogen components to form said first and said second solutions, respectively, wherein said first solution is a thrombin solution and said second solution is a fibrinogen solution and said multicomponent biological adhesive is a fibrin sealant.

13. The applicator system according to claim 12, wherein said sterile water is hermetically sealed within said piston-reservoir assembly by providing distal and proximal seals to said distal ends of said two pistons and to proximal ends of said two pistons, respectively.

14. The applicator system according to claim 13, wherein said distal and proximal seals are manufactured from silicone.

15. The applicator system according to claim 1, wherein said piston-reservoir assembly is manufactured from polypropylene.

16. The applicator system according to claim 1, wherein said loading unit assembly is manufactured from ABS plastics.

17. A kit for dispensing a first solution and a second solution of a multicomponent biological adhesive, the kit comprising:

at least two piston assemblies each having a piston matingly engaging a reservoir storing a fluid therein, each of said pistons having fluid communication means for providing fluid communication between a corresponding one of said reservoirs and a distal end of said pistons for communicating said fluid stored within said reservoirs to said distal end of said pistons;

a loading unit assembly having a movable piercing shuttle, said movable piercing shuttle having a first end configured for coupling to said at least two piston assemblies and a second end configured for coupling to at least two vials each storing a component of said multicomponent biological adhesive, said loading unit assembly further having fluid communication means for communicating said fluid from said distal end of said pistons to an interior of each of said at least two vials by distally moving said reservoirs towards said pistons to mix said fluid with said components stored within said at least two vials to form said first and second solutions, said fluid communication means of said loading unit assembly further communicating said first and second solutions from said interior of each of said at least two vials to said reservoirs by proximally moving said reservoirs away from said pistons; and

a dispensing unit assembly having at least two conduits each configured to align with a corresponding one of said fluid communication means of each of said pistons when coupling said dispensing unit assembly to said distal ends of said at least two piston assemblies, wherein said first and second solutions are dispensed by said dispensing unit assembly by distally moving said reservoirs towards said pistons.

18. The kit according to claim 17, wherein said dispensing unit assembly includes piercing means for piercing a seal fitted on each of said distal ends of said two pistons.

19. The kit according to claim 17, wherein said dispensing unit assembly is configured for performing laparoscopic surgical procedures.

20. The kit according to claim 19, wherein said piercing means includes two needles having a bore therethrough, said bore of each of said two needles being in fluid communication with said at least two conduits.

21. The kit according to claim 17, further comprising a check-valve assembly having at least two check-valves configured for fitting at each of said distal ends of said two pistons.

22. The kit according to claim 21, wherein each of said at least two check-valves includes a bore therethrough for providing fluid communication between said fluid communication means of said two pistons and said fluid communication means of said loading unit assembly.

23. The kit according to claim 21, wherein each of said at least two check-valves includes a valve for preventing fluid communication through each of said bores.

24. The kit according to claim 21, wherein said dispensing unit assembly is configured for being coupled to said at least two check-valves to align said at least two conduits of said dispensing unit assembly with a corresponding one of said two bores of said at least two check-valves for providing fluid communication between said bores of said at least two check-valves and said at least two conduits of said dispensing unit assembly.

25. The kit according to claim 17, wherein said component stored by one of said at least two vials is thrombin and said component stored by another of said at least two vials is fibrinogen.

26. The kit according to claim 25, wherein said fluid stored within each of said reservoirs is sterile water capable of being communicated from said reservoirs to said interior of each of said at least two vials to mix said sterile water with said thrombin and fibrinogen to form said first and said second solutions, respectively, wherein said multicomponent biological adhesive is a fibrin sealant.

27. The kit according to claim 26, wherein said sterile water is hermetically sealed within said at least two piston assemblies by providing distal and proximal seals to said distal ends of said two pistons and to proximal ends of said two pistons, respectively.

28. The kit according to claim 27, wherein said distal and proximal seals are manufactured from silicone.

29. The kit according to claim 17 wherein said at least two piston assemblies are manufactured from polypropylene.

30. The kit according to claim 17, wherein said loading unit assembly is manufactured from ABS plastics.

31. The kit according to claim 17, wherein said dispensing unit assembly includes a plurality of ultrasonically welded components.

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专利名称(译)	纤维蛋白密封剂涂抹器系统		
公开(公告)号	US20030055384A1	公开(公告)日	2003-03-20
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摘要(译)

提供纤维蛋白密封剂涂敷器系统用于分配第一和第二蛋白质溶液以形成生物粘合剂，其克服了现有技术的缺点。第一和第二蛋白质溶液优选是纤维蛋白原和凝血酶溶液，其可以在施用部位或施用器内混合以形成纤维蛋白密封剂。根据本发明的纤维蛋白密封剂涂敷器系统包括两个活塞型子组件，其耦合到两个通过耦合单元存储纤维蛋白原和凝血酶的小瓶。活塞式子组件将消毒水储存在储存器内，储存器通过耦合单元与小瓶流体连通。将水压入小瓶中以形成纤维蛋白原和凝血酶溶液。然后将溶液吸入储液器中，并将Y型耦合器连接到活塞式子组件的远端.Y型耦合器提供储液器和喷嘴体之间的流体连通，用于在产生远端压力时分配溶液。在储存器内迫使溶液朝向喷嘴主体。