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ABSTRACT

An apparatus (5) for mixing two components and delivering the mixture to a patient contains a mixing chamber (100) for mixing a liquid component and a powder component by rotation of a collapsible mixing element (160). A plunger (210) is then advanced through the mixing chamber (100) to force the mixture out of the mixing chamber (100) and deliver the mixture to the patient.

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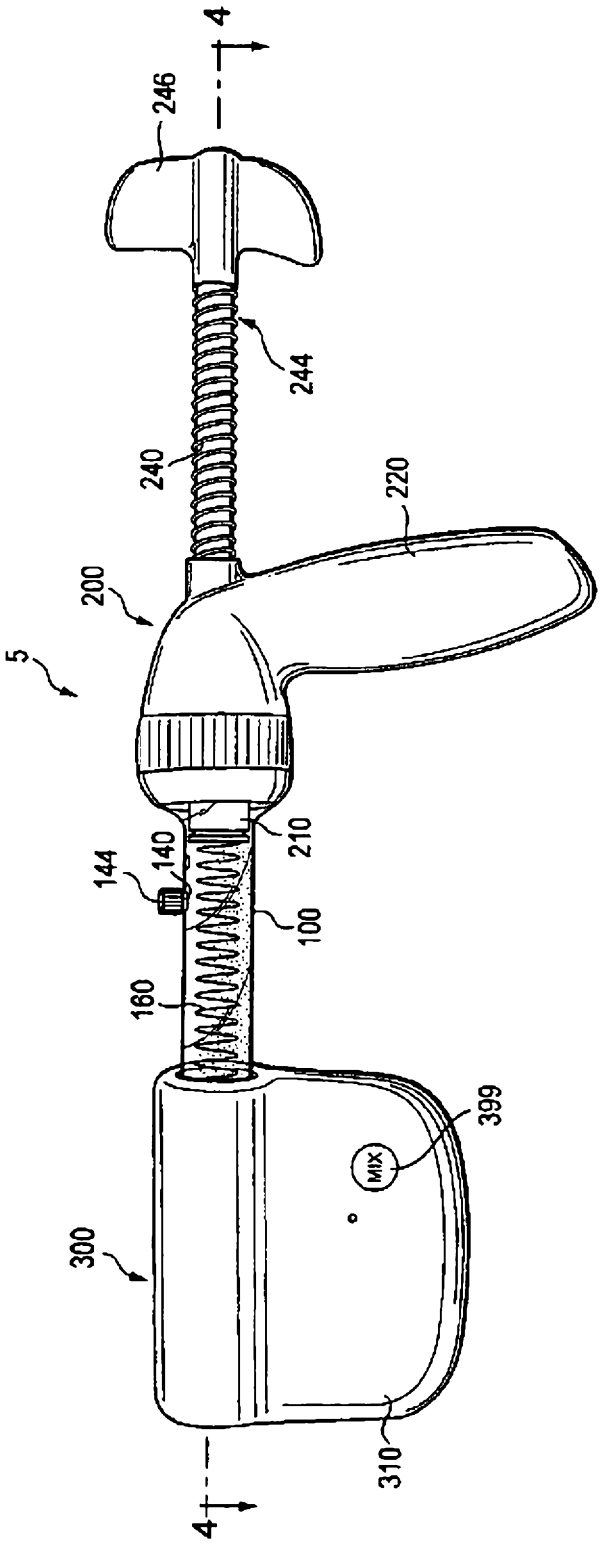

FIG. 1

Regulation 3.2
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ORIGINAL

COMPLETE SPECIFICATION

TO BE COMPLETED BY THE APPLICANT

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The following statement is a full description of this invention including the best method of performing it known to us:-

CURABLE MATERIAL MIXING AND DELIVERY DEVICE

[0001] 1. Technical Field.

[0002] The present invention relates to devices and methods for mixing curable materials for use with stabilizing bone structures. More particularly, it relates to devices, systems and methods for mixing the components that form the curable materials.

[0003] 2. Background Information

[0004] Surgical intervention at damaged or compromised bone sites has proven highly beneficial for patients, for example patients with back pain associated with vertebral damage. Bones of the human skeletal system include mineralized tissue that can generally be categorized into two morphological groups: "cortical" bone and "cancellous" bone. Outer walls of all bones are composed of cortical bone, which has a dense, compact bone structure characterized by a microscopic porosity. Cancellous or "trabecular" bone forms the interior structure of bones. Cancellous bone is composed of a lattice of interconnected slender rods and plates known by the term "trabeculae."

[0005] During certain bone procedures, cancellous bone is supplemented by an injection of a palliative (or curative) material employed to stabilize the trabeculae. For example, superior and inferior vertebrae in the spine can be beneficially stabilized by the injection of an appropriate, curable material (e.g., polymethylmethacrylate (PMMA) or other curable material). In other procedures, percutaneous injection under computed tomography (CT) and/or fluoroscopic guidance of stabilization material into vertebral compression fractures by, for example, transpedicular or parapedicular approaches, has proven beneficial in relieving pain and stabilizing damaged bone sites. Other skeletal bones (e.g., the femur) can be treated in a similar fashion. In any regard, bone in general, and cancellous bone in particular, can be strengthened and stabilized by a palliative injection of bone-compatible curable material.

[0006] The curable material used in the above procedures is typically fashioned by mixing a liquid component and a powder component within the

operating room just prior to placement of the curable material into an injector wherein the injector is then used to introduce the curable material into the patient. Curable material may be prepared by mixing a very fine cement powder, typically PMMA, with a liquid monomer, typically methylmethacrylate.

[0007] According to mixing methods of the prior art, the components of the curable material are mixed in a mixing bowl and then transferred to a delivery system, such as a syringe or other injector, to deliver the curable material to the patient. This method can delay procedures while the cement is being transferred to the delivery system and the curable material may be spilled during the transfer. The delay increases procedure time and can cause the curable material to set before the procedure is completed. Additionally, the mixing of the components creates undesirable fumes that have an offensive odor to many. The mixing of the components in an open mixing bowl exposes the operating room to obnoxious fumes. Further, mixing is typically done by hand by the physician. Hand mixing can be tedious and unpredictable, resulting in potentially poor quality curable material.

[0008] There exists a need in the medical device field for an improved curable material mixing and delivery device. The present invention provides an efficient device and method for mixing and delivering components of a curable material.

BRIEF SUMMARY

[0009] One aspect of the present invention is directed to a device for mixing two components and dispensing a mixture. The device has a mixer section that defines a mixing chamber having a first end and a second end. The device also has a mixing element holder at the first end of the mixing chamber wherein the mixing element holder defines a passageway between the mixing chamber and the exterior of the mixing chamber. The device further has a collapsible mixing element connected with the mixing element holder and operative to mix a first component and a second component within the mixing chamber. The device also has a plunger operative to substantially seal against an interior surface of the mixing chamber wherein the collapsing mixing element collapses at the first end

as the plunger is advanced from the second end to the first end and the mixture is dispensed through the passageway in the mixing element holder.

[0010] In another aspect of the present invention, a device for mixing two components is provided. In this embodiment, the device has a mixing barrel defining a mixing chamber. The device also has a liquid component introduction port on the mixing barrel for introducing a liquid component into the mixing chamber. The device further has a spring holder within the mixing chamber. The device also has a spring connected with the spring holder operative to rotate about a longitudinal axis of the mixing chamber wherein the spring is the only means for substantially mixing the liquid component and a powder component within the mixing chamber.

[0011] In yet another aspect of the present invention, a device for mixing two components to form a mixture is provided. The device has a mixer section defining a mixing chamber. The device also has a collapsible mixing element holder within the mixing chamber wherein the collapsible mixing element holder defines a passageway between the mixing chamber and the exterior of the mixing chamber. The device also has a collapsible mixing element connected to the collapsible mixing element holder operative to rotate about a longitudinal axis of the mixing chamber. The device also has a drive shaft operative to engage the passageway of the collapsible mixing element holder wherein rotation of the drive shaft causes rotation of the collapsible mixing element holder.

[0012] In yet another aspect of the present invention, a method of mixing a first component and a second component in a mixing chamber having a mixing element and dispensing mixed curable material is provided. The method has a step of loading a powder component into the mixing chamber, the mixing chamber having a first end and a second end. The method also has a step of loading a liquid component into the mixing chamber. The method further has the step of inserting a drive shaft into the first end of the mixing chamber. The method also has the step of causing the mixing element to rotate by rotating the drive shaft and mixing the first component with the second component and forming a mixture. The method also has the step of inserting a plunger into the second end of the

mixing chamber. The method further has the step of advancing the plunger toward the first end of the mixing chamber, the plunger applying force to the mixture. The method also has the step of dispensing the mixture from the first end of the mixing chamber.

[0013] In still another aspect of the present invention, a device for introducing liquid component into a mixing chamber is provided. The device has an elongated ampule holder having a longitudinal axis and having a chamber operative to hold an ampule. The device also has at least one breaker pin slidably received within an opening of the ampule holder wherein rotational movement of the ampule holder causes the at least one breaker pin to move radially inward and pierce an ampule when the ampule is present in the ampule holder.

[0014] Advantages of the present invention will become more apparent to those skilled in the art from the following description of the preferred embodiments of the invention which have been shown and described by way of illustration. As will be realized, the invention is capable of other and different embodiments, and its details are capable of modification in various respects. Accordingly, the drawings and description are to be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] Figure 1 is a side view of an assembled curable material mixing device according to a preferred embodiment of the present invention;

[0016] Figure 2 is an exploded view of the mixer section according to a preferred embodiment of the present invention;

[0017] Figures 3a and 3b are perspective views of a mixing element holder according to a preferred embodiment of the present invention;

[0018] Figure 4 is a partial cross-section view of an assembled curable material mixing device according to a preferred embodiment of the present invention taken along line 4-4 of Figure 1;

[0019] Figure 5a is a perspective view of a driver connecter according to a preferred embodiment of the present invention;

[0020] Figure 5b is a cross-section view of a driver connecter according to the preferred embodiment of the present invention depicted in Figure 5a taken along line 5b-5b of Figure 5a;

[0021] Figure 6a is a partial exploded view of an injector according to a preferred embodiment of the present invention;

[0022] Figure 6b is a partial cross-section view of an assembled injector according to the preferred embodiment of the present invention depicted in Figure 6a taken along line 6b-6b of Figure 6a;

[0023] Figure 7 is a partial cross-section view of a curable material mixing device according to a preferred embodiment of the present invention during delivery of the mixed curable materials;

[0024] Figure 8a is a perspective view of a liquid component delivery system according to a preferred embodiment of the present invention;

[0025] Figure 8b is a cross-section view of a liquid component delivery system according to the preferred embodiment of the present invention depicted in Figure 8a taken along line 8b-8b of Figure 8a;

[0026] Figures 9a and 9b are perspective views of a cam according to a preferred embodiment of the present invention;

[0027] Figure 10 is an exploded view of a liquid component delivery system according to a preferred embodiment of the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS AND THE PRESENTLY PREFERRED EMBODIMENTS

[0028] FIG. 1 illustrates components of a curable material mixing and delivery system **5** according to principles of the present invention. The curable material mixing and delivery system **5** according to a preferred embodiment of the present invention has a mixer section **100** for mixing components of a curable material, an injector **200** for driving curable material out of the mixer section **100** and a driver **300** for mixing the components of the curable material within the mixer section **100**. According to one preferred embodiment, and with reference to FIGS. 8-10,

the system also includes a liquid component delivery system **400** for delivering a liquid component to the mixer section **100**.

[0029] Details on the various components are provided below. In general terms, however, two separate components, preferably a liquid component and a powder component, are required to be mixed to form curable material for delivery to a injection site within a patient. With reference to FIG. 1, the mixer section **100** is loaded with a first component, preferably the powder component. The second component, typically a liquid component, is delivered to the mixer section **100** through an introduction port **140** into the mixer section **100**. The driver **300** is then activated to rotate a collapsible mixing element **160** within the mixer section **100** to mix the first and second components into the curable material. After mixing, the driver **300** is removed, and a plunger **210** of the injector **200** advances axially within the mixer section **100** to dispense curable material from the mixer section **100** and into a delivery site within a patient. The system **5** can be used for a number of different procedures, including, for example, vertebroplasty and other bone augmentation procedures in which curable material is delivered to a site within bone.

[0030] The system **5**, and in particular the mixer section **100**, is highly useful for mixing a curable material. The phrase "curable material" within the context of the substance that can be delivered by the system/device of the invention described herein is intended to refer to materials (e.g., composites, polymers, and the like) that have a fluid or flowable state or phase and a hardened, solid or cured state or phase. Curable materials include, but are not limited to injectable bone cements (such as PMMA), which have a flowable state wherein they can be delivered (e.g., injected) by a cannula to a site and subsequently cure into hardened curable material. Other materials, such as calcium phosphates, bone in-growth material, antibiotics, proteins, etc., could be used to augment the curable material (but should not affect an overriding characteristic of the resultant formulation having a flowable state and a hardened, solid or cured state).

[0031] With reference to FIG. 2, a mixer section **100** according to a preferred embodiment is disclosed. The mixer section **100** comprises a housing **110** that

defines a mixing chamber **115**. The housing **110** further comprises an first end **120** that has an opening **125** to the mixing chamber **115** and a second end **130** that has an opening **135** to the mixing chamber. The housing also contains a port **140** that defines a passageway **145** to the mixing chamber **115**.

[0032] According to a preferred embodiment depicted in FIG. 2, the housing **110** is generally cylindrical and defines a longitudinal axis. The first end **120** and second end **130** are at opposite ends of the housing with respect to the longitudinal axis. The first end **120** further defines an end shoulder **126** and a cylindrical reduced diameter cylindrical section **127** with respect to the diameter of the mixing chamber **115**. According to a preferred embodiment, the reduced diameter cylindrical section **127** also contains threads **128** for mating with corresponding threads on a cap **119** or cannula connector (not shown). The second end **130** preferably defines a substantially conical section **136** having an inner mating surface **137**. The second end further defines a cylindrical ring **138** extending axially from the conical section **136**. Preferably, the cylindrical ring **138** contains one or more injector locking features **139** that correspond to one or more openings **171** within the collar **170** so that the collar **170** may be removably connected with the housing **110**. In this embodiment, after the collar **170** is inserted over the cylindrical ring **138**, the collar **170** is rotated slightly to removably lock the collar **170** to the housing **110**. As will be described in detail below, the injector locking features **139** also correspond to openings in the injector **200** to removably attach the housing to the injector **200**. Preferably, the injector locking features **139** and corresponding openings **171** are keyed so that the collar **170** can be attached to the housing **110** in one preferred orientation. Although this embodiment uses injector locking features **139** to connect the housing **110** with the collar **170**, one skilled in the art would know that other attachment means, such as a threaded connect or press-fit connection, may also be used.

[0033] A port **140** is located at a radial outer surface of the housing **110**. The port **140** preferably contains a cylindrical projection **142** and defines a passageway **145** to the mixing chamber **115**. The port may also contain threading **143** so that the port may connect with a cap **144** or other device having corresponding

threading. The port **140** is preferably located proximal to the second end **130** of the housing **110**. Pressure within the mixing chamber **115** can become significant when the curable material is being dispensed from the mixing chamber **115**. As will be explained in more detail below, the plunger **210**, as depicted in FIG. 4, of the injector **200** will advance axially within the mixing chamber **115** to dispense the curable material. Large pressures within the mixing chamber **115** are not generally created until the plunger **210** has moved axially within the mixing chamber **115** toward the first end **120** of the housing **110** and until the curable material is substantially compacted within the first end **120** of the housing **110**. In order to avoid dispensing material through the port **140**, the port **140** is preferably located at a position toward the second end **130** of the housing **110**. In this way, the plunger **210** will preferably pass beyond the location of the port **140** before the formation of significant pressure within the mixing chamber **115**.

[0034] With reference to FIG. 2, the housing also contains one or more vents **170** for releasing gas from within the mixing chamber **115**. Preferably, the one or more vents **170** are located on the radial outer surface of the housing **110**. The vents **170** are preferably covered with a filter material so that gas escaping from the mixing chamber **115** has a reduced odor that is associated with the curable material. Preferably, the filter material is a Gore-tex® covering. Other filtering material, such as charcoal filtering material, may also be used. In order to avoid dispensing curable material through the one or more vents **170**, the one or more vents **170** are preferably located at a position toward the second end **130** of the housing **110**. In this way, the plunger **210** will preferably pass beyond the location of the one or more vents **170** before the formation of significant pressure within the mixing chamber **115**.

[0035] With reference to FIG. 2, according to one preferred embodiment, the housing **110** also contains one or more driver locking features **190** to aid in removably connecting the housing **110** with the driver **300**. Preferably, the driver locking features **190** are located on the radial outer surface of the housing **110**. In this embodiment, the driver locking features project **190** radially from the housing and define one or more faces **192** perpendicular to the longitudinal axis of the

mixing chamber. As will be described in more detail below, the projections **190** correspond to openings **360** in the driver connector **350** of the driver, as depicted in FIG. 5b. Preferably, the driver locking features **190** and corresponding driver connector openings are keyed so that the driver **300** can be attached to the housing **110** in one preferred orientation. Although this embodiment uses locking projections **190** to connect the housing with the driver **300**, one skilled in the art would know that other attachment means, such as a threaded connect or press-fit connection, may also be used.

[0036] With reference to FIG. 2, the inner surface **117** of the housing **110** also defines one or more shallow grooves **195**. The one or more grooves **195** are preferably located proximal to the second end **130** of the housing and are operative to allow air or other gas to travel around the plunger **210** as the plunger **210** advances axially through the mixing chamber **115**.

[0037] The housing **110** is preferably transparent to provide the physician the ability to see the contents of the mixing chamber **115**. This will allow the physician to see the progress of the mixing step of the components and to visually inspect the consistency of the curable material. The housing is preferably made of cyclic olefin copolymer (COC), but may also be made of nylon, polycarbonate, Lexan®, and any other transparent material suitable for use with curable material, suitable for use at significant pressure, and suitable to withstand sterilization. With continued reference to FIG. 2, the housing **110** preferably also contains visual indicia **199** to indicate the volume of the curable material within the mixing chamber **115**. The visual indicia **199** may be molded onto the housing **110**, or may painted or otherwise printed on the housing **110**.

[0038] The mixer section **100** also has mixing element holder **150** and a collapsible mixing element **160** for mixing the components of the curable material. The mixing element holder **150** connects to the collapsible mixing element **160** and both are located at least partially within the mixing chamber **115**. With reference to FIGS. 3a and 3b, according to a preferred embodiment, the mixing element holder **150** contains a disk-shaped portion **151** and a reduced diameter slotted projection **152**. A first end **153** of the mixing element holder contains a

collapsible mixing element retaining ring **154** for fixedly retaining the collapsible mixing element **160.** In one embodiment, the mixing element holder **150** contains a retaining slot **155** that is perpendicular to the longitudinal axis of the mixing chamber **115**. This slot **155** retains a perpendicular projection of the collapsible mixing element **160** as to fixedly retain the collapsible mixing element **160** from moving rotationally with respect to the mixing element holder **150**. With continued reference to FIG. 3b, and reference to FIG. 4, a second surface **156** of the mixing element holder **150** engages the inner surface of the shoulder **126** of the first end **120** of the housing **110**. The mixing element holder **150** further defines a passageway **157** that is operative to allow curable material to flow from within the mixing chamber **115** to outside the mixing chamber **115**. The slotted projection **152** of the mixing element holder **150** preferably extends within the reduced diameter cylindrical section **127** of the first end **120** of the housing **110**. According to a preferred embodiment, the slotted projection **152** comprises two projections separated by a slot **158** that is coaxial with the passageway.

[0039] With reference to FIGS. 3b and 4, the slotted projection **152** and passageway **157** are operative to removably engage a drive shaft **340** of the driver **300**. The drive shaft **340** and the mixing element holder **150** interact so that rotation of the drive shaft **340** rotates the mixing element holder **150** and thus, the collapsible mixing element **160**. In the preferred embodiment depicted in FIGS. 3a and 3b the slotted projections **152** and the passageway **157** of the mixing element holder **150** form hexagonal surfaces that are operative to engage a hexagonal drive shaft **340**. In another embodiment, the drive shaft may be similar in shape to a flat-ended screw driver and the mixing element holder may define a corresponding slot. One skilled in the art will know other suitable configurations to allow the drive shaft **340** to rotationally drive the mixing element holder **150** in a removable manner.

[0040] With reference to FIGS. 3b and 4, in one preferred embodiment the slotted projection **152** contains one or more fingers **159** that extend perpendicularly to the longitudinal axis of the mixing chamber **115**. The one or more fingers mate with corresponding surfaces in the reduced diameter cylindrical

section **127** of the housing **110** that are also perpendicular to the longitudinal axis of the mixing chamber. In this embodiment, the mixing element holder **150** is substantially retained from moving axially within the mixing chamber **115**. In the embodiment where the projections are separated by a slot **158**, one skilled in the art will understand that when the mixing element holder **150** is placed within the mixing chamber **115**, the slot **158** between the projections **152** allow the projections to bend toward each other so that the fingers **159** may be inserted through the reduced diameter section **127** at the first end **120** of the housing **110**. The reduced diameter section **127** is adapted so that when the mixing element holder **150** is fully inserted into the housing **110**, the projections **152** snap outward and the fingers **159** engage the corresponding surfaces of the housing **110** that are perpendicular to the longitudinal axis of the mixing chamber **115**.

[0041] With reference to FIG. 4, according to one preferred embodiment, the collapsible mixing **160** element extends substantially the entire length of the mixing chamber **115**. As will be described in more detail below, the collapsible mixing element **160** mixes the components of the curable material when the collapsible mixing element **160** is rotated about the longitudinal axis of the mixing chamber **115**. The collapsible mixing element **160** is also operative to collapse within the mixing chamber **115** as the plunger **210** is moved axially within the chamber **115**.

[0042] According to the preferred embodiment of FIG. 2, the collapsible element is a spring-like element having a wire diameter from approximately 0.010 inches to approximately 0.050 inches (approximately 0.254 mm to approximately 1.27 mm) and more preferably, approximately 0.024 inches (approximately 0.61mm). The collapsible mixing element **160** is also preferably made of stainless steel. In this embodiment, the diameter of the collapsible mixing element **160** is preferably slightly less than the diameter of the mixing chamber **115** to prevent the collapsible mixing element **160** from locking against the inner surface **117** of the housing **110**. A radial clearance of zero inches to approximately 0.5 inches (approximately 12.7 mm) may be used, and more preferably a clearance of approximately 0.045 inches (approximately 1.14 mm) is used. Additionally,

according to one preferred embodiment, the outer diameter of the spring should be approximately 0.578 inches (approximately 14.68 mm)to approximately 0.618 inches (approximately 15.70 mm), and is more preferably 0.598 inches (approximately 15.19 mm). Non-spring-like collapsible mixing elements may also be used. In one preferred embodiment, the collapsible mixing element is one or more loops extending within the mixing chamber. In an embodiment having two or more loops, the collapsible mixing element forms a whisk-like configuration. In another preferred embodiment, the collapsible mixing element is a single somewhat flexible, substantially straight element, such as a wire, that may be connected to the mixing element holder off-center of the holder. In this embodiment, rotation of the mixing element holder causes the element to rotate and whip within the chamber. In another preferred embodiment, the collapsible mixing element is two or more somewhat flexible, substantially straight elements, such as wires, wherein rotation of the mixing element holder causes the elements to rotate and whip within the chamber. In another preferred embodiment, the collapsible mixing element is at least one curved element extending substantially the entire length of the mixing chamber. The above mixing element embodiments are operative to bend and otherwise collapse within the mixing chamber when engaged by an advancing plunger. One skilled in the art will understand that each of these embodiments can be used alone, in combination with a spring-like element, or in combination with each other.

[0043] According to a preferred embodiment depicted in FIG. 2, the mixer section **100** also comprises a removable collar 170 connected to the housing **110**. In this embodiment, the collar **170** is removably connected with the second end of the housing **110** and acts as cap on the housing **110** for transportation and storage. The collar contains a stopper **172** operative to seal the second end of the housing **110**. The stopper **172** preferably is substantially the same diameter of the mixing chamber and forms a seal so that component material does not escape around the stopper **172**.

[0044] The mixing section also comprises a removable cap **119** that may be attached to the reduced diameter section **127** of the housing **110** during

transportation and storage. The cap **119** is removed prior to use to allow the driver **300** to be attached to the housing **110**.

[0045] With reference to FIG. 4, the curable material mixing and delivery system **5** also comprises a removable driver **300**. The driver **300** provides the force to rotate the collapsible mixing element **160** to mix the components of the curable material. In a preferred embodiment according to FIG. 4, the driver **300** comprises a shell **310** for conveniently manipulating the driver **300**. The driver **300** further comprises a battery **320**, a motor **330** and drive shaft **340** within the shell **310**. The driver **300** also comprises a driver connector **350** for connecting the mixer device **100** with the driver **300**. Preferably, the driver connector **350** is located at an opening on the shell **310** and is operative to receive an end of the mixer section **100**. In one preferred embodiment depicted in FIGS. 5a and 5b, the driver connecter **350** provides a support for the motor **330** and the drive shaft **340** and provides the corresponding openings **360** for receiving the driver locking features **190** of the housing **110**. In this embodiment, the motor **330** is located in an opening **370** at a first end **372** of the driver connector **350**. A drive shaft **340** is connected to the motor **330** and extends through a divider **355** and into an **380** opening at the second end **382** of the driver connector **350**. An O-ring **390** is preferably located at the intersection of the drive shaft **340** and divider **355** to prevent gas or curable material to escape from the mixer device **100** when the mixer section **100** is connected with the driver **300**. The driver connector **350** further defines one or more grooves **365** for receiving the driver locking features **190** of the housing **110**, and thus removably connecting the driver connector **350** with the housing **110**. The driver locking features **190** of the housing **110** are operative to be inserted into the one or more openings **360** and grooves **365** of the driver connector **350** and rotated to removably lock the mixer section **100** with the driver **300**. Preferably, the driver locking features **190** and corresponding driver connector openings **360** and grooves **365** are keyed so that the driver can be attached to the mixer device in one preferred orientation.

[0046] With reference to FIG. 4, the drive shaft **340** is operative to rotate the mixing element holder **150** of the mixer section **100**. In a preferred embodiment,

the drive shaft **340** is hexagonal and the slotted projections **152** and the passageway **157** of the mixing element holder **150** form corresponding female hexagonal surfaces. In another embodiment, the drive shaft may be similar in shape to a flat-ended screw driver and the mixing element holder defines a corresponding slot. One skilled in the art will know other suitable configurations to allow the drive shaft to rotationally drive the mixing element holder.

[0047] The driver motor **330** may be activated in various ways. According to one preferred embodiment, a button **399**, depicted in FIG. 1, is located at an opening in the shell **310** to activate the motor **330** when depressed.

[0048] With reference to FIGS. 1 and 4, the curable material mixing and delivery system **5** also comprises an injector **200**. The injector provides the force to advance the plunger **210** axially within the mixer section **100** and deliver curable material to a delivery site. According to one preferred embodiment, the injector **200** comprises a grip section **220** to allow a physician to conveniently manipulate the injector **200**. In this embodiment, the injector **200** further comprises an internal threaded portion **230** and a threaded rod **240**. The threaded rod **240** contains a first end **242** proximal to the plunger **210**. The threaded rod also contains a second end **244** distal from the plunger and having a handle **246**. The threaded rod **240** and internal threaded section **230** are operative so that when the handle **246** is turned, the threaded rod **240** moves axially in the direction of the first end **120** of the mixer section **100**. As the threaded rod **240** moves axially, it advances the plunger **210** axially within the mixing chamber **115**.

[0049] The injector further comprises an interface to connect to the second end **130** of the housing **110** in a fashion similar to the manner the first end **120** of the housing **110** removable connected to the driver **300**. In one embodiment, one or more injector locking features **139** of the second end **130** of the housing **110** correspond to openings and grooves in the injector **200** to removably connect the injector **200** with the housing **110**. The injector locking features **139** of the housing **110** are operative to be inserted into the one or more openings of the injector **200** and rotated within a groove to removably lock the mixer section **100** with the injector **200**. Preferably, the injector locking features **139** and

corresponding openings and grooves of the injector **200** are keyed so that the injector can be attached to the housing **110** in one preferred orientation. Although this embodiment uses injector locking features **139** to connect the housing **110** with the injector **200**, one skilled in the art will understand that other attachment means, such as a threaded connect or press-fit connection, may also be used.

[0050] According to one preferred embodiment depicted is FIGS. 6a and 6b, the injector **200** further comprises a release **800** to allow the threaded rod **240** to be indexed axially quickly without requiring the rod **240** to be rotated. In this embodiment, internal threaded section **810** are operative to disengage from the threaded rod **240** to allow the rod **240** to slide freely axially. According to one preferred embodiment of the injector **200** depicted in FIGS. 6a and 6b, the injector release **800** comprises two internal threaded sections **810** that are operative to engage the threaded rod **240**. Each internal threaded section contains two posts **814**. The threaded sections **810** are contained within a rotatable container **820**. The rotatable container **820** is comprised of two container halves **822**. Each container half **822**contains two radially oriented slots **824** operative to receive the posts **814** of the internal threaded sections **810** when the container halves **822** are connected together. In this embodiment, the internal threaded sections **810** are slidable within the rotatable container **820**. The posts **814** of the internal threaded sections **810** extend to outside of rotatable container **820**. The injector release **800** also comprises a shoulder **830** having two guide fins **832** and a first pair of transverse slots **834**. The guide fins **832** are operative to hold the rotatable container **820**, but allow rotation of the rotatable container **820** therein. A post **814** of internal threaded section **810** extends through the transverse slots **834** of the shoulder **830**. The injector release **800** also comprises a threaded rod guide **850**. The threaded rod guide **850** defines a center opening operative to receive and support the threaded rod **240** and defines a second pair of transverse slots **852**. The threaded rod guide **850** is operative to fit within the guide fins **832** of the shoulder **830**. A post **814** of each internal threaded section **810** extends through the transverse slots **852** of the threaded rod guide **850**. An injector collar **860** fits over the guide fins **832** of the shoulder **830** and is operative to rotate around the

guide fins **832** of the shoulder **830**. The injector collar **860** also engages the rotatable container **820** such that rotation of the injector collar **860** rotates the rotatable container **820** within the guide fins **832**. Rotation of the rotatable container **820** causes the posts **814** to slide translationally within the transverse slots **834, 852**. Because the posts **814** are also constrained by the radial slots **824** of the rotatable container **820**, translational movement causes the internal threaded sections **810** to move radially within rotatable container **820**. Rotation of the injector collar **860** thus causes the internal threaded sections **810** to radially move in or out from the threaded rod **240**. When the internal threaded sections **810** are positioned radially outward from the threaded rod **240**, the threaded rod **240** is disengaged from the internal threaded sections **810** and can freely move axially. When the internal threaded sections **810** are position radially inward from the threaded rod **240**, the threaded rod **240** is engaged with the internal threaded sections **810** and must be turned to move axially.

[0051] In operation of the device according to the present invention, the curable material delivery system **5** is preferably prepackaged in a kit. In a first step the mixer section **100**, driver **300** and injector **200** are assembled to form the curable material delivery device **5**. According to one preferred embodiment, the mixer section **100** is prepackaged with a predetermined volume of powder component. In another embodiment the removable cap **119**, removable collar **170** or removable port cap **144** may be removed from the housing **110** to allow powder component to be introduced into the mixing chamber **115**. It is understood by one skilled in the art that the powder component may be comprised of additives additional to powder polymer. The additives include other materials, such as calcium phosphates, bone in-growth material, antibiotics, and proteins.

[0052] In a preferred embodiment where the powder component had been preloaded into the mixing chamber **115**, the removable cap **119** is removed and the driver **300** is connected to the first end **120** of the housing **110**. When connecting the driver **300** to the housing, the drive shaft **340** of the housing must be inserted into the passageway **157** of the mixing element holder **150** so that the drive shaft **340** engages and rotates the mixing element holder **150** when the drive shaft **340** is

rotated. The removable collar **170** is also removed and the injector **200** is connected to the second end **130** of the housing **110**. It is understood that care should be taken avoid spilling the powder component contents from the housing when the cap or collar are removed from the housing. When connecting the injector **200** to the housing **110**, the plunger **210** should be in a retracted position so that the liquid component can be introduced into the mixing chamber **115** through the port **140**.

[0053] After the driver **300** and injector **200** are connected to the housing **110**, the port cap **144** is removed from the port **140** and the liquid component is introduced into the mixing chamber **115**. Devices for introducing liquid component into the mixing chamber are described in detail below. According to one embodiment, the port cap **144** is then placed back onto the port **144**. After introduction of the liquid component the curable material components are ready to be mixed. Preferably, the physician activates the motor **330** of the driver **300**, causing the drive shaft **340** to rotate rapidly. Rotation of the drive shaft **340** causes the mixing element holder **150** and the collapsible mixing element **160** to also rotate rapidly. The components are mixed until the mixture contains the optimum properties for the desired application. For an embodiment using PMMA loaded with barium sulphate, the components are preferably mixed between approximately 30 and approximately 150 seconds and are more preferably mixed for approximately 90 seconds. According to one preferred embodiment, the driver **300** is pre-programmed to cycle through a predetermined mixing sequence. In this embodiment, the physician need only press the mix button **399** and the driver **300** will automatically mix the materials according to a predetermined length of time, speed and rotational direction to obtain the optimum properties of the curable material. According to one preferred embodiment, the mixing element **160** is rotated by the driver **300** in a first direction for a predetermined period of time, and then rotated in the opposite direction for a predetermined period of time. In another preferred embodiment, rotational direction alternates during the mixing cycle.

[0054] After the components are mixed the driver **300** is removed from the first end **120** of the housing **110**. According to one preferred embodiment depicted in FIG. 7, the first end **120** of the housing **110** is then connected to a cannula **700** for delivery of curable material to a delivery site within a patient.

[0055] With reference to FIGS. 4, after the driver is removed, the plunger **210** is advanced axially within the chamber **115** toward the first end **120**. According to a preferred embodiment, the mixed curable material does not occupy the entire volume of the mixing chamber **115**. As a result, gas pockets **710** exist within the mixing chamber **115**. As the plunger **210** is advanced within the mixing chamber **115** toward the first end **120** of the housing **110**, gas is allowed to escape through one or more grooves **195** on the inner surface of the housing **110** toward the second end **130** of the housing **110** and rearward of the plunger **210**. The grooves **195** advantageously allows gas to be removed from the curable material as the plunger **210** advances and compresses the curable material. The removal of gas from the curable material beneficially provides a more consistent curable material and more efficient delivery of curable material. According to another preferred embodiment, gas is also allowed to escape from the mixing chamber **115** through filtered vents **170** on the housing. It will be appreciated by one skilled in the art that the injector plunger **210** may be more easily advanced when the curable material contains gas pockets **710** and is thus less dense. As the gas is removed from the curable material, the curable material becomes more dense and greater force is required to advance the plunger **210**. According to one preferred embodiment described above, the threaded rod **240** may be released from the internal threaded sections **230** of the injector **200**. In this embodiment the plunger **210** may be quickly pushed toward the first end **120** of the housing **110** to compress the curable material and remove gas from the curable material. When high resistance from dense curable material is experienced, the internal threaded section **230** can be caused to engage the threaded rod **240**, and the plunger **210** can be further advanced by rotating the handle **246** on the threaded rod **240**.

[0056] With reference to FIG. 7, as the plunger **210** is indexed toward the first end **120** of the housing **110**, the plunger **210** engages the collapsible mixing

element **160** and causes the collapsible mixing element **160** to collapse within the first end **120** of the housing **110**. Additionally, as the plunger **210** is indexed toward the first end **120** of the housing **110**, curable material is forced through the passageway **157** in the mixing element holder **150** and curable material is thus dispensed from the first end **120** of the housing **110**.

[0057] Various manners can be utilized to deliver the liquid component for mixing with a powder component. According to one prior art method, an ampule **410** (by way of example, see FIG. 8a) filled with liquid component can be broken to deliver the liquid component. The ampule is typically made of a brittle casing, such as glass, that can be broken to release the liquid component. An ampule **410** typically comprises a body **412**, a neck **414**, and a tip **416**. In this method, the neck **414** is typically scored to allow a physician to break the tip **416** from the body **412** by hand. The contents of the body **412** may then be emptied into a mixing bowl. In this prior art method, however, the ampule **410** may crumble in the physician's hands, exposing the physician to sharp objects, obnoxious fumes, and causing the liquid contents to be spilled.

[0058] According to one preferred embodiment of the present invention, and with reference to FIGS. 8a and 8b, the curable material mixing and delivery system **5** also comprises a liquid component delivery system **400** for delivering a liquid component to the mixing chamber **115**. In the embodiment depicted in FIGS. 8a and 8b, an ampule **410** is placed inside of a syringe-like assembly wherein the ampule **410** can be broken and the liquid component delivered to the mixing chamber **115** in a closed system. The physician is thus not required to handle the ampule to break it and is not exposed to the fumes and odor associated with the liquid component. The liquid component delivery system **400** according to the preferred embodiment of FIGS. 8a and 8b comprises a syringe barrel **420**, a cam **440** and a liquid component plunger **450**. The syringe barrel **420** is preferably cylindrical and comprises a larger diameter section **422** and a reduced diameter section **426** connected by a transition section **424**. The inner surface of the syringe barrel **420** defines one or more guide ridges **425** protruding from the inner surface of the syringe barrel and extending longitudinally along a section of

the barrel **420**. The syringe barrel **420** is preferably transparent to provide the physician with a visual indication of the location of the liquid component plunger **450** and the contents of the ampule **410**. The syringe barrel **420** is preferably made of polyethylene. According to one preferred embodiment, the reduced diameter section has a filter **429** to filter glass particles from the broken ampule but allow the liquid component to pass therethrough.

[0059] The liquid component plunger **450** is operative to being inserted into the syringe barrel **420**. The liquid component plunger **450** contains an inner ampule compartment **452** for holding an ampule **410**. The liquid component plunger **450** also contains one or more openings **454** operative to slidably hold one or more breaker pins **456**. Each breaker pin preferably contains one or more o-rings **458** to prevent liquid component from flowing around the breaker pins **456**. The liquid component further comprises a groove **460** to accommodate an o-ring **462**. The o-ring **462** prevents fumes and odors associated with the liquid component from escaping the system. The liquid component plunger **450** also comprises a plunger tip **464** proximal to the output end **428** of the syringe barrel **420**. The plunger tip **464** is preferably cylindrical and is substantially the same diameter of reduced diameter section **426** of the syringe barrel **420** so that the tip **464** is capable of creating a seal between the tip **464** and the reduced diameter section **426** of the syringe barrel **420**. The plunger tip **464** is preferably made of a flexible material and is preferably press fit onto the end of the liquid component plunger **450**. The liquid component plunger **450** also contains a removable cap **468** that is placed over the ampule compartment **452** to hold the ampule **410** in place and further provide a seal for fumes or odors. The liquid component plunger **450** also comprises the cam **440**. The cam **440** is attached to the liquid component plunger **450** proximal to the breaker pin openings **454** and is operative to allow the liquid component plunger **450** to rotate relative to the cam **440**.

[0060] With reference to FIGS. 9a and 9b, the cam **440** is generally cylindrical and contains at its center an opening to allow the liquid component plunger **450** to pass there through. One or more guide ridges **425** of the syringe barrel **420** engage one or more interface grooves **442** on the cam. The cam **440** is positioned within

the syringe barrel **420** such that the guide ridges prevent the cam **440** from rotating within the syringe barrel **420**. Inner cam surfaces **444** of the cam **440** define a generally oval shape. The generally oval shape of the cam surfaces **444** allow the ampule breaker pins **456** to extend outside of the liquid component plunger **450** when the liquid component plunger **450** is in a first orientation. When the liquid component plunger **450** is rotated 90 degrees to a second orientation, the breaker pins **456** slide along the cam surfaces **444** from the wide inner section **445** of the cam **440** to the narrow inner section **447** and thus drive the breaker pins **456** toward the center of the liquid component plunger **450**.

[0061] In operation of the liquid component delivery system **400**, the liquid component plunger **450** and cam **440** are positioned within the syringe barrel **420**. The liquid component plunger **450** is preferably position axially within the syringe barrel **420** so that the plunger tip **464** is within the larger diameter section **422** of the syringe barrel **420** and just above the transition region **424**. The liquid component plunger **450** is in the first orientation to allow the breaker pins **456** to extend outside of the liquid component plunger **450** and into the wider inner section **445** of the cam **440**. An ampule **410** is placed inside of the ampule compartment **462**. When the liquid component plunger **450** is in the first orientation the tip of the ampule **410** is located between the breaker pins **456**. The cap **468** is then placed onto the liquid component plunger **450**.

[0062] According to one preferred embodiment, the liquid component delivery system **400** is then attached to the mixer section **100**. Preferably, the liquid component delivery system **400** is oriented vertically above the mixer section **100** to allow liquid component to flow by gravity into the mixer section **100** after the ampule **410** is broken. After attachment to the mixer section **100**, the liquid component plunger **450** is rotated 90 degrees relative to the syringe barrel **420**. As the liquid component plunger **450** is rotated 90 degrees, the breaker pins **456** slide along the cam surfaces **444** and are forced inward. The breaker pins **456** thus move toward the center of the liquid component plunger **450** as the breaker pins **456** travel from the wider inner section **445** of the cam **440** to the narrow inner section **447** of the cam **440**. The inward motion of the breaker pins **456** cause the

tips of the breaker pins **456** to penetrate the tip **416** of the ampule **410** and release the liquid component.

[0063] By gravity, the liquid component flows into the reduced diameter section **426** of the syringe barrel **420**. The liquid component plunger **450** is then axially pushed so that the plunger tip **464** engages the inner surface of the reduced diameter section **426** of the syringe barrel **420**. Continued downward motion creates pressure in the syringe barrel **420** that further assists in forcing the liquid component into the mixer section **100**.

[0064] According to another preferred embodiment of the present invention, and with reference to FIG. 10, the curable material mixing and delivery system **5** comprises a liquid component delivery system **500** for delivering a liquid component to the mixing chamber **115**. In this embodiment, an ampule is broken by hand, however, protections are provided to the physician. The liquid component delivery system **500** comprises a base **510**, a protective sleeve **520** and a cap **530**. The base **510** is preferably cylindrical and defines a chamber **515** operative to hold the body **412** of an ampule **410**. The protective sleeve **520** is operative to fit over the tip **416** of an ampule **410**. The protective sleeve **520** is preferably made of a durable material capable of resisting puncture by sharp objects. The cap **530** is preferably cylindrical and defines a chamber **535** operative to hold the body **412** of an ampule **410**. The cap **530** also contains a needle section **540**. The needle section **540** is operative to engage a port **140** on a mixing chamber **115** to deliver liquid component to a mixing chamber **115**. According to one preferred embodiment, the needle section **540** also comprises a valve **545** to inhibit the flow of liquid through the needle section **540**.

[0065] In operation of this embodiment, an ampule **410** is placed inside of the chamber **515** of the base **510**. The protective sleeve **520** is placed over the tip **416** of the ampule **410**. Preferably with the sleeve **520** and tip **416** in one hand and the base **510** and body **412** in the other hand, the physician breaks the ampule tip **416** from the ampule body **412**. The cap **530** is then placed over the body **412** of the ampule **410**, and the cap **530** and base **510** are connected with each other. Preferably the cap **530** and base **510** are press fit with each other, however, one

skilled in the art will understand other suitable means for connecting the cap **530** and base **510**. The liquid component delivery system **500** is then inverted so that liquid component may flow by gravity into the needle section **530**. The liquid component delivery system **500** is then connected to a port **140** in flow communication with a mixing chamber **115** to deliver liquid component to the mixing chamber **115**.

[0066] It is therefore intended that the foregoing detailed description be regarded as illustrative rather than limiting, and that it be understood that it is the following claims, including all equivalents, that are intended to define the spirit and scope of this invention.

INDUSTRIAL APPLICABILITY

[0067] The system and method answers a long felt need for increasing safety and control in the mixing and administration of curable material to a patient by providing a closed mixing and delivery device wherein material may be dispensed directly from a mixing chamber. The mixing chamber includes a collapsible mixing element that mixes the components of the curable material and collapses within the mixing chamber as a plunger forces cement outside of the mixing chamber.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A device for mixing two components and dispensing a mixture comprising: a mixer section defining a mixing chamber having a first end and a second end; a mixing element holder at the first end of the mixing chamber wherein the mixing element holder defines a passageway between the mixing chamber and the exterior of the mixing chamber; a collapsible mixing element connected with the mixing element holder and operative to mix a first component and a second component within the mixing chamber; and a plunger operative to substantially seal against an interior surface of the mixing chamber wherein the collapsing mixing element collapses at the first end as the plunger is advanced from the second end to the first end, and the mixture is dispensed through the passageway in the mixing element holder.

2. The device of claim 1 wherein the collapsible mixing element is a spring.

3. The device of claim 1 wherein the mixer section defines a reduced diameter section proximal to the first end of the mixing chamber and at least a portion of the mixing element holder is positioned within the reduced diameter section.

4. The device of claim 1 wherein the mixing chamber defines a longitudinal axis and the collapsible mixing element is operative to mix the first component and the second component by rotating around the longitudinal axis.

5. The device of claim 1 wherein the plunger is connected to an injector having a handle and the plunger advances in the mixing chamber by rotating the handle.

6. A device for mixing two components comprising: a mixing barrel defining a mixing chamber; a liquid component introduction port on the mixing barrel for introducing a liquid component into the mixing chamber; a spring holder within the mixing chamber; a spring connected with the spring holder operative to rotate about a longitudinal axis of the mixing chamber wherein the spring is the only means for substantially mixing the liquid component and a powder component within the mixing chamber.

7. The device of claim 6 wherein the spring holder defines a passageway between the mixing chamber and the exterior of the mixing chamber.

8. The device of claim 7 wherein mixing of the first component and second component forms a curable material and the passageway is operative to dispense the curable material.

9. The device of claim 8 further comprising a plunger operative to substantially seal against an interior surface of the mixing chamber wherein the spring collapses at an end proximal to the spring holder as the plunger is advanced from the end distal to the spring holder to the end proximal to the spring holder.

10. The device of claim 9 wherein the plunger is connected with an injector having a rotatable handle and the plunger advances in the mixing chamber by rotating the handle.

11. The device of claim 6 wherein the mixing barrel is transparent.

12. The device of claim 6 wherein liquid component is delivered through the liquid component introduction port by a liquid delivery device comprising: an ampule containing a volume of liquid; an elongated ampule holder having a longitudinal axis and having a chamber operative to hold the ampule; at least one breaker pin slidably received within an opening of the ampule holder wherein rotational movement of the ampule holder causes the breaker pin to move radially inward and pierce the ampule.

13. The device of claim 6 wherein liquid component is delivered through the liquid component introduction port by a liquid delivery device comprising: an ampule containing a volume of liquid, the ampule at least partially broken; a base; and a cap removably attached to the base, the cap and base defining a chamber operative to hold the ampule, the cap having an output end for dispensing the liquid.

14. A device for mixing two components to form a mixture comprising: a mixer section defining a mixing chamber; a collapsible mixing element holder within the mixing chamber wherein the collapsible mixing element holder defines a passageway between the mixing chamber and the exterior of the mixing chamber; a collapsible mixing element connected to the collapsible

mixing element holder operative to rotate about a longitudinal axis of the mixing chamber; and a drive shaft operative to engage the passageway of the collapsible mixing element holder wherein rotation of the drive shaft causes rotation of the collapsible mixing element holder.

15. The device of claim 14 wherein the collapsible mixing element is a spring.

16. The device of claim 14 further comprising a plunger operative to substantially seal against an interior surface of the mixing chamber wherein the collapsible mixing element collapses at an end proximal to the mixing element holder as the plunger is advanced from the end distal to the mixing element holder to the end proximal to the mixing element holder.

17. The device of claim 16 wherein the plunger is connected with an injector having a rotatable handle and the plunger advances in the mixing chamber by rotating the handle.

Dated this 15 day of November 2010

Care Fusion 2200, Inc.
Patent Attorneys for the Applicant
PETER MAXWELL AND ASSOCIATES

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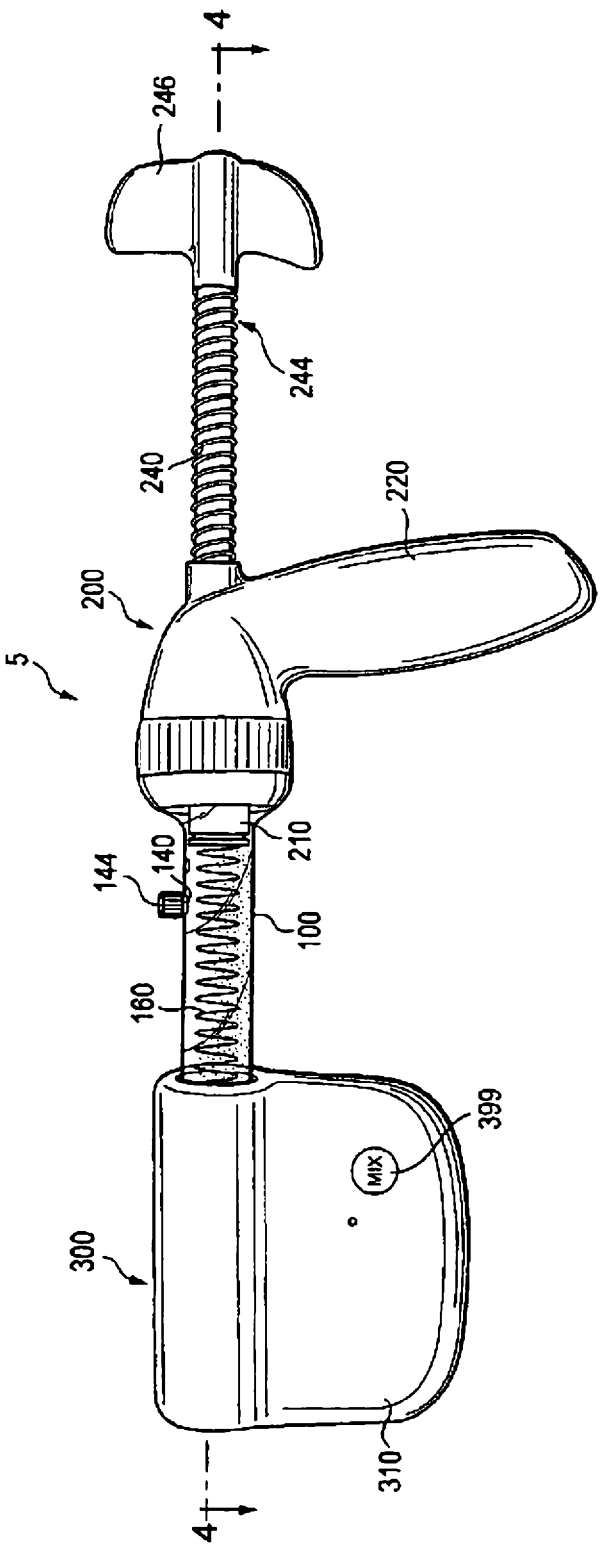

FIG. 1

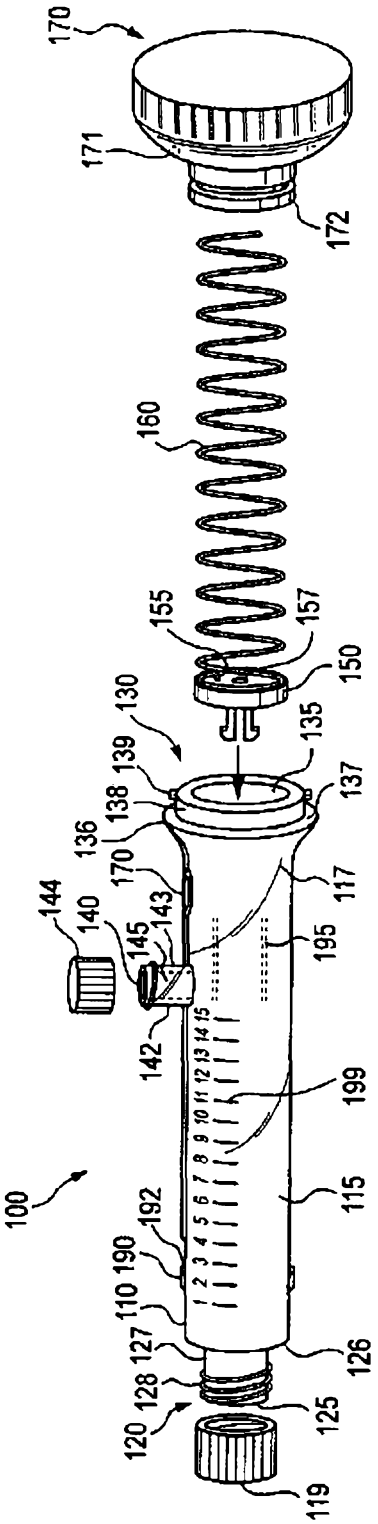
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FIG. 2

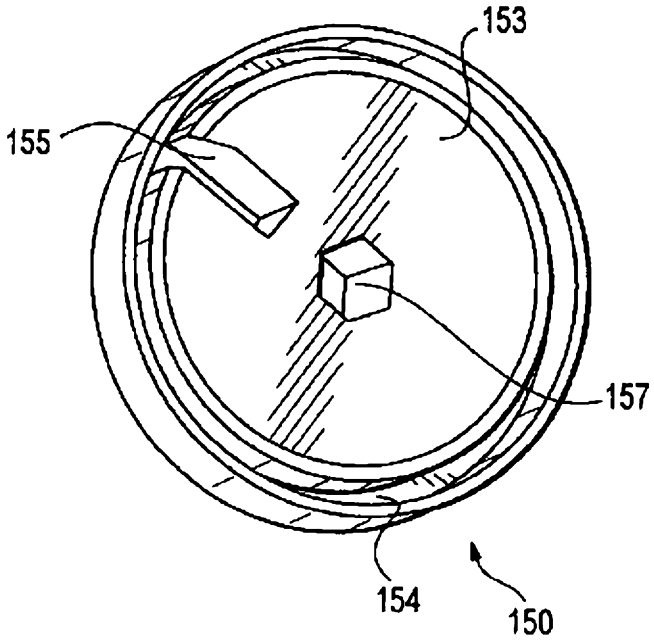


FIG. 3a

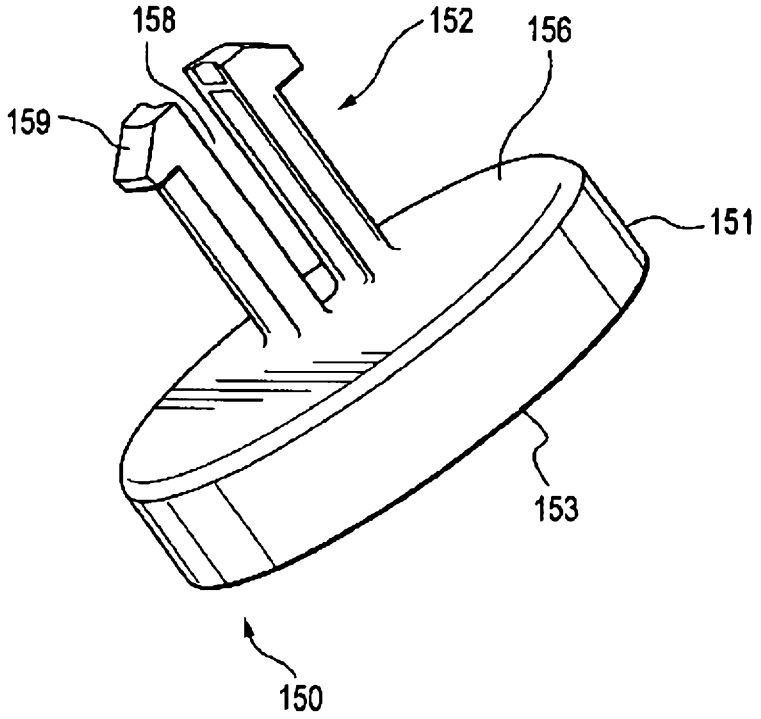
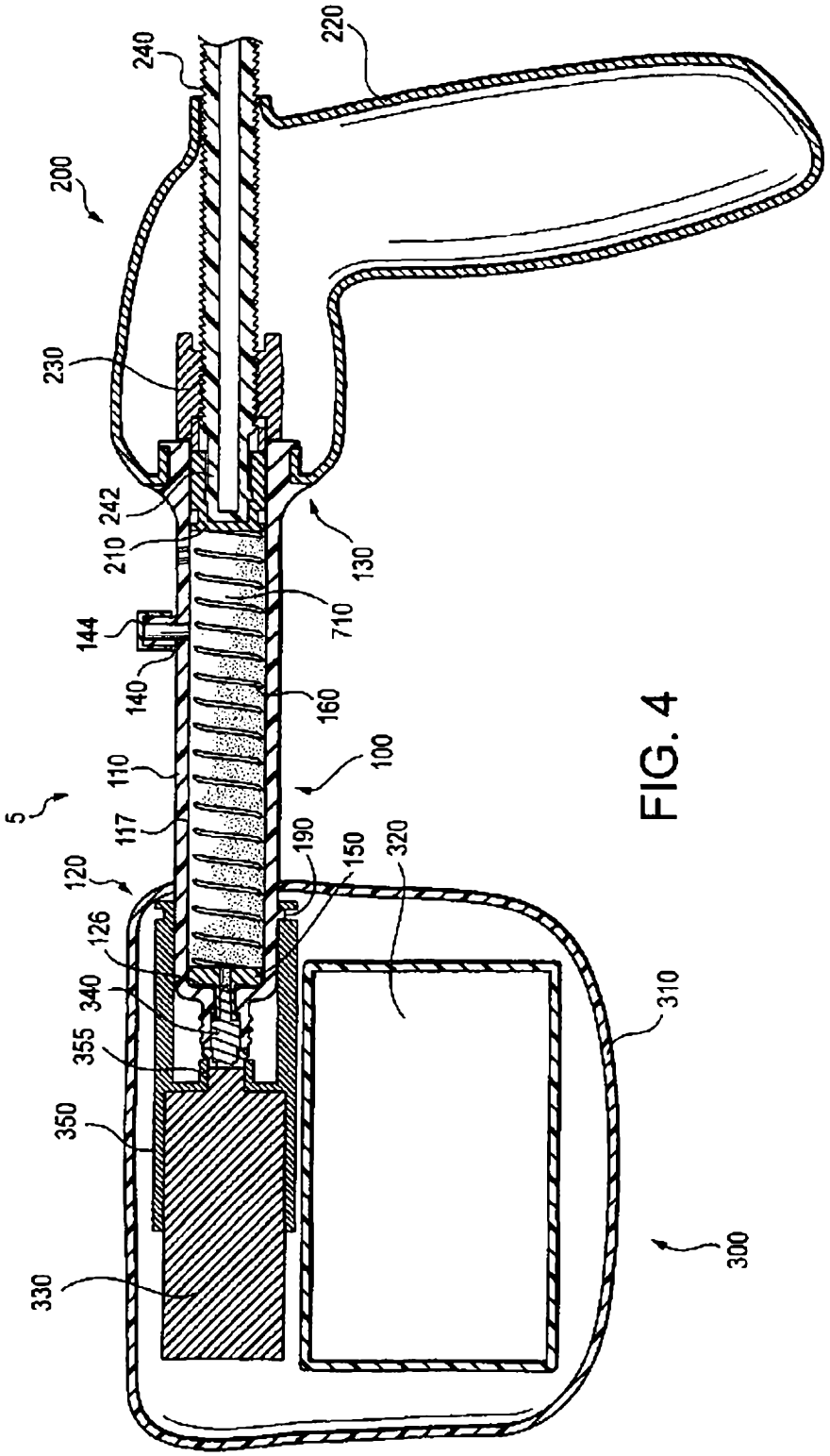


FIG. 3b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710
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310
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330
300

FIG. 4

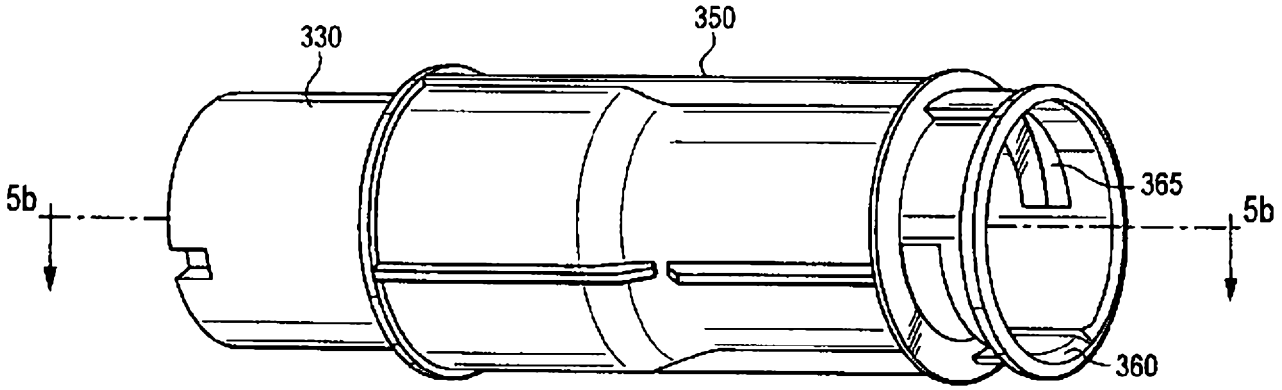


FIG. 5a

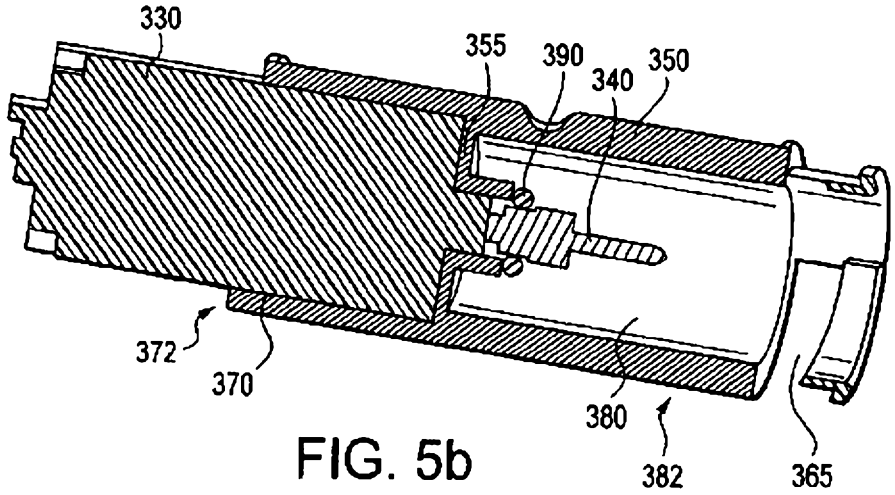
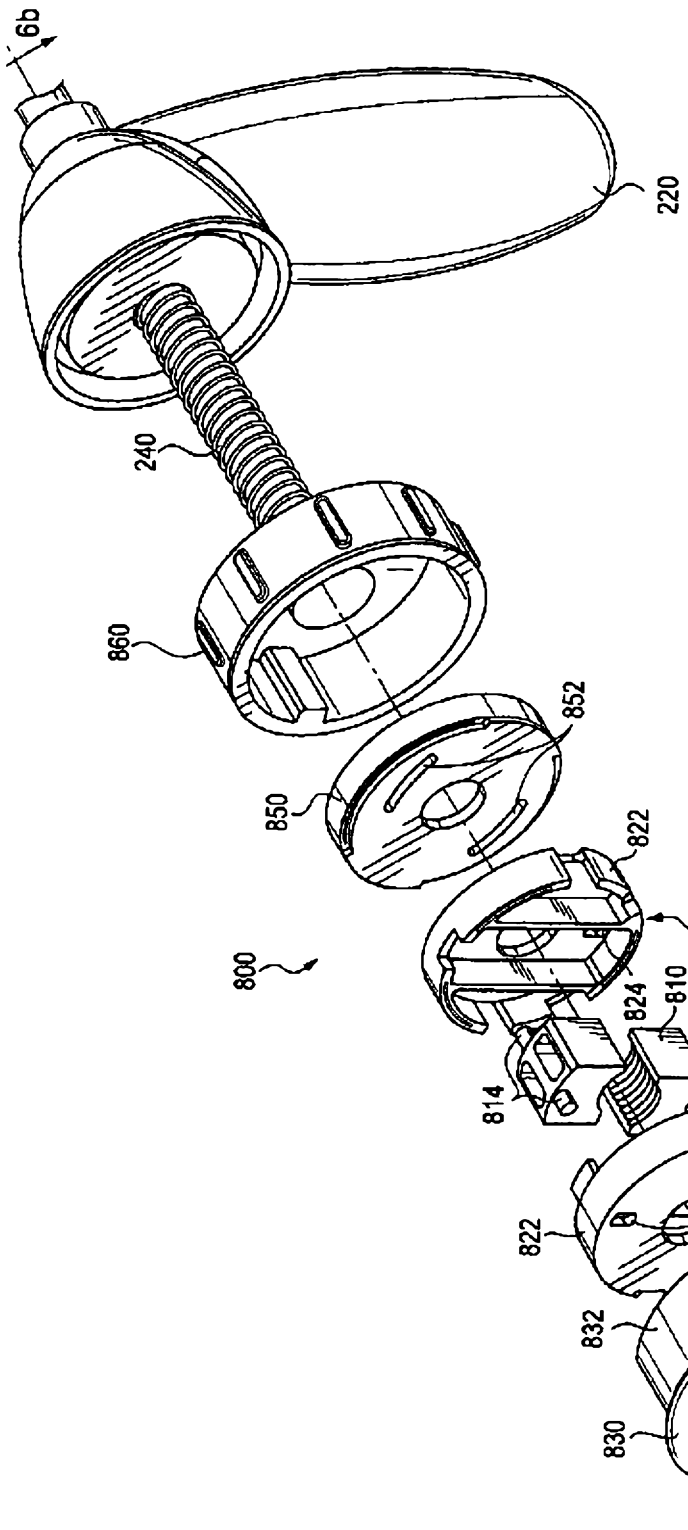


FIG. 5b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814
820
822
824
832
832
830
834
6b

FIG. 6a

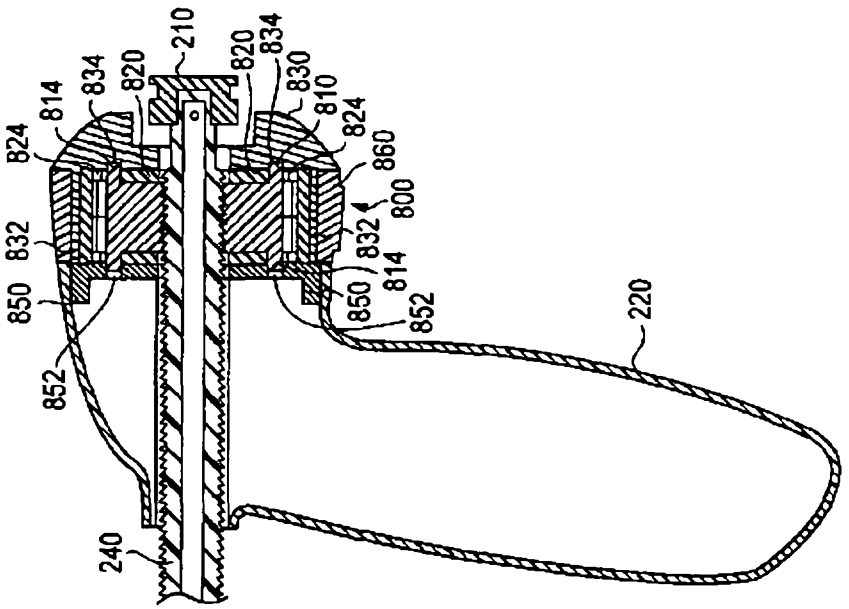

FIG. 6b

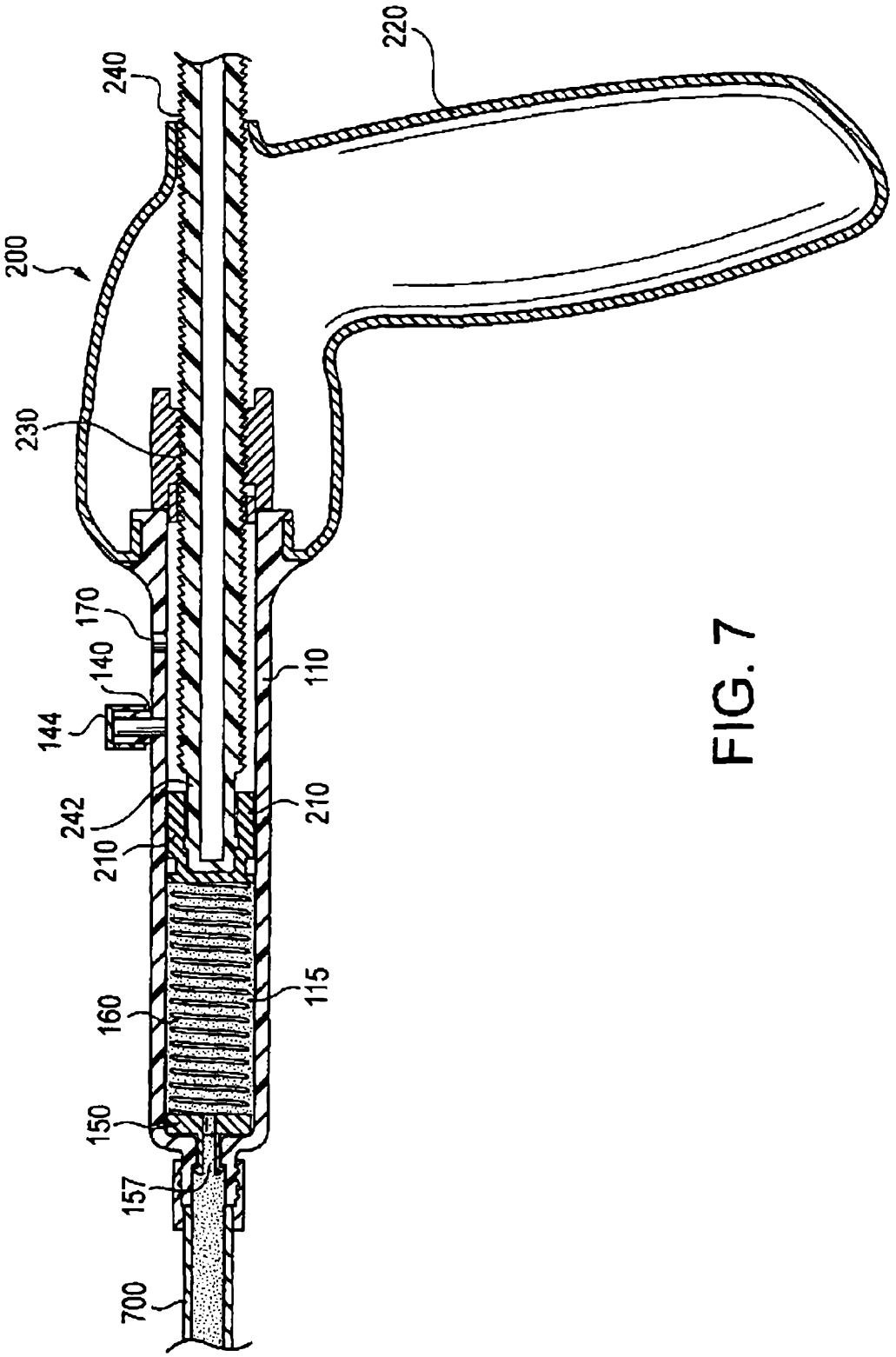

FIG. 7

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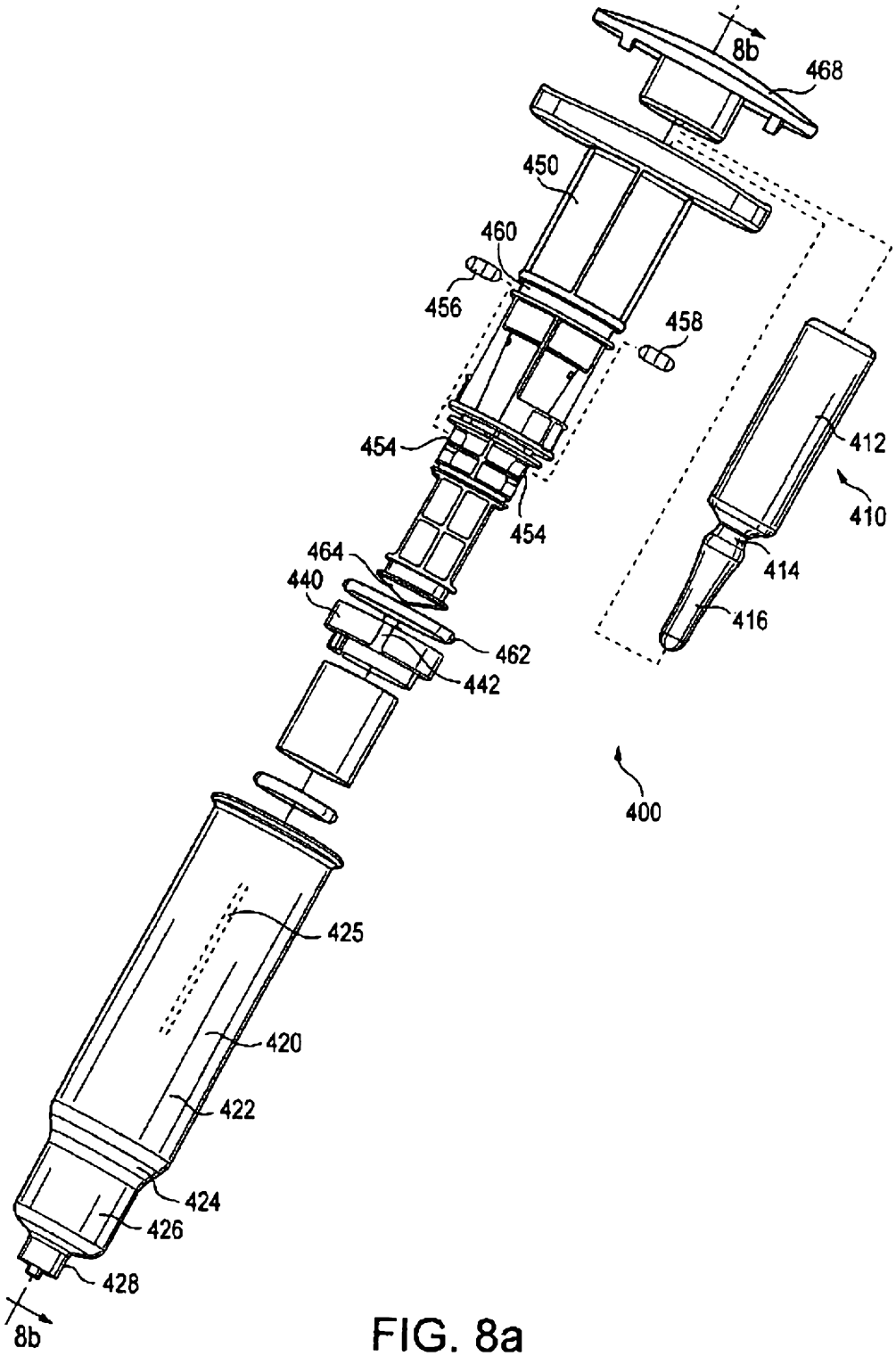

FIG. 8a

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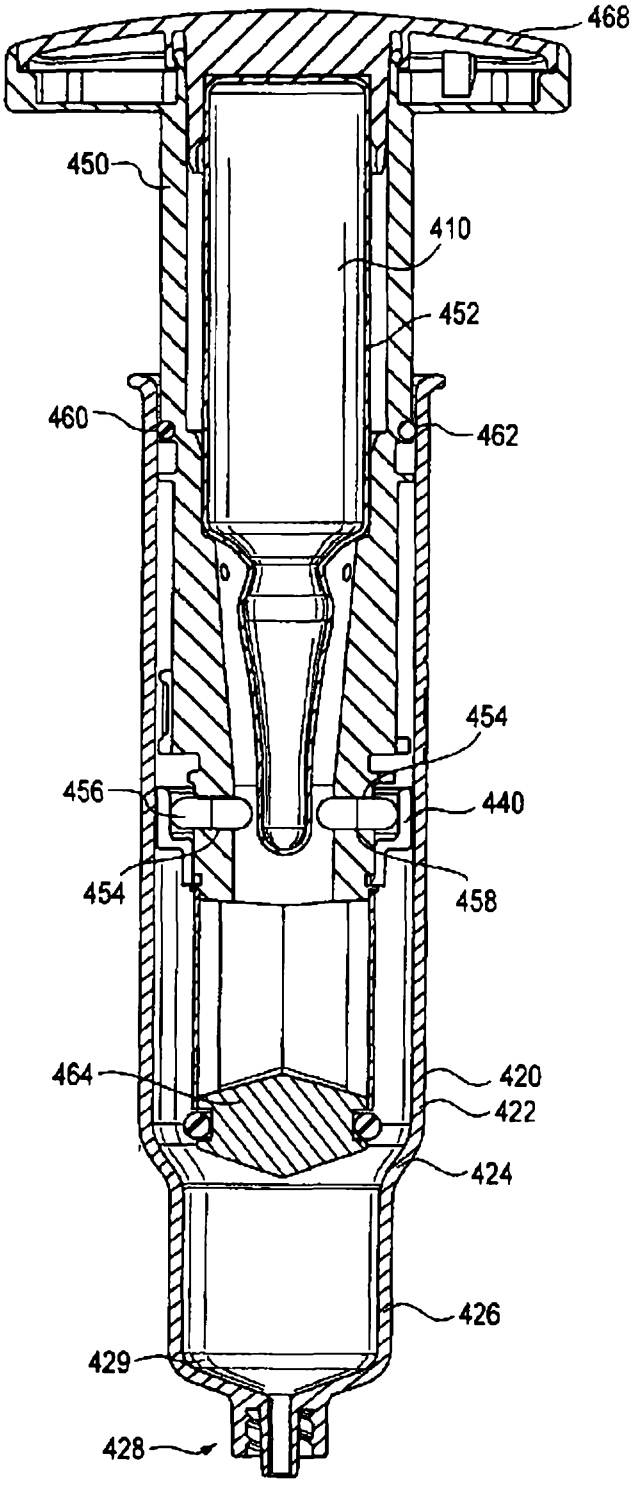

FIG. 8b

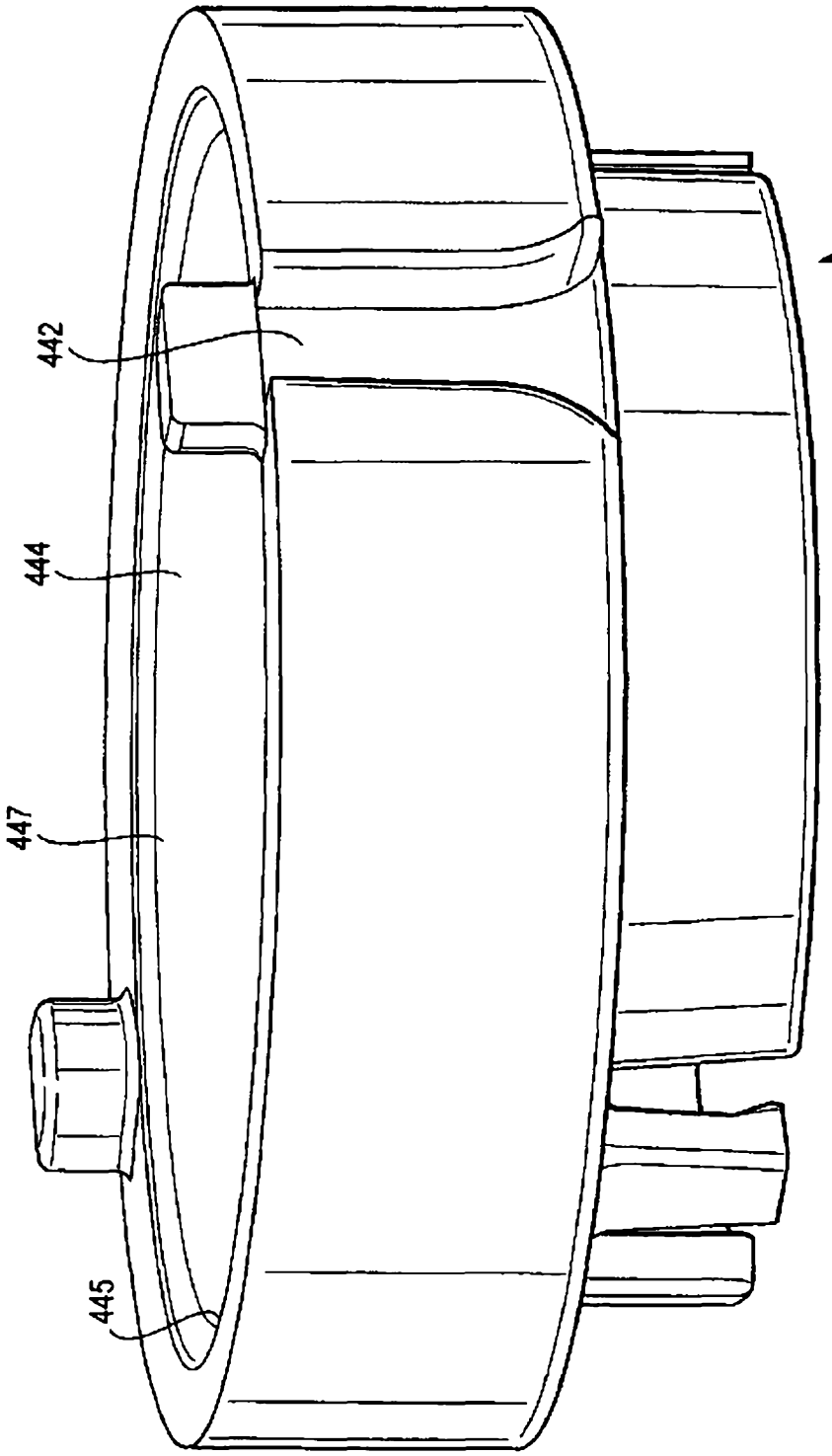

FIG. 9a

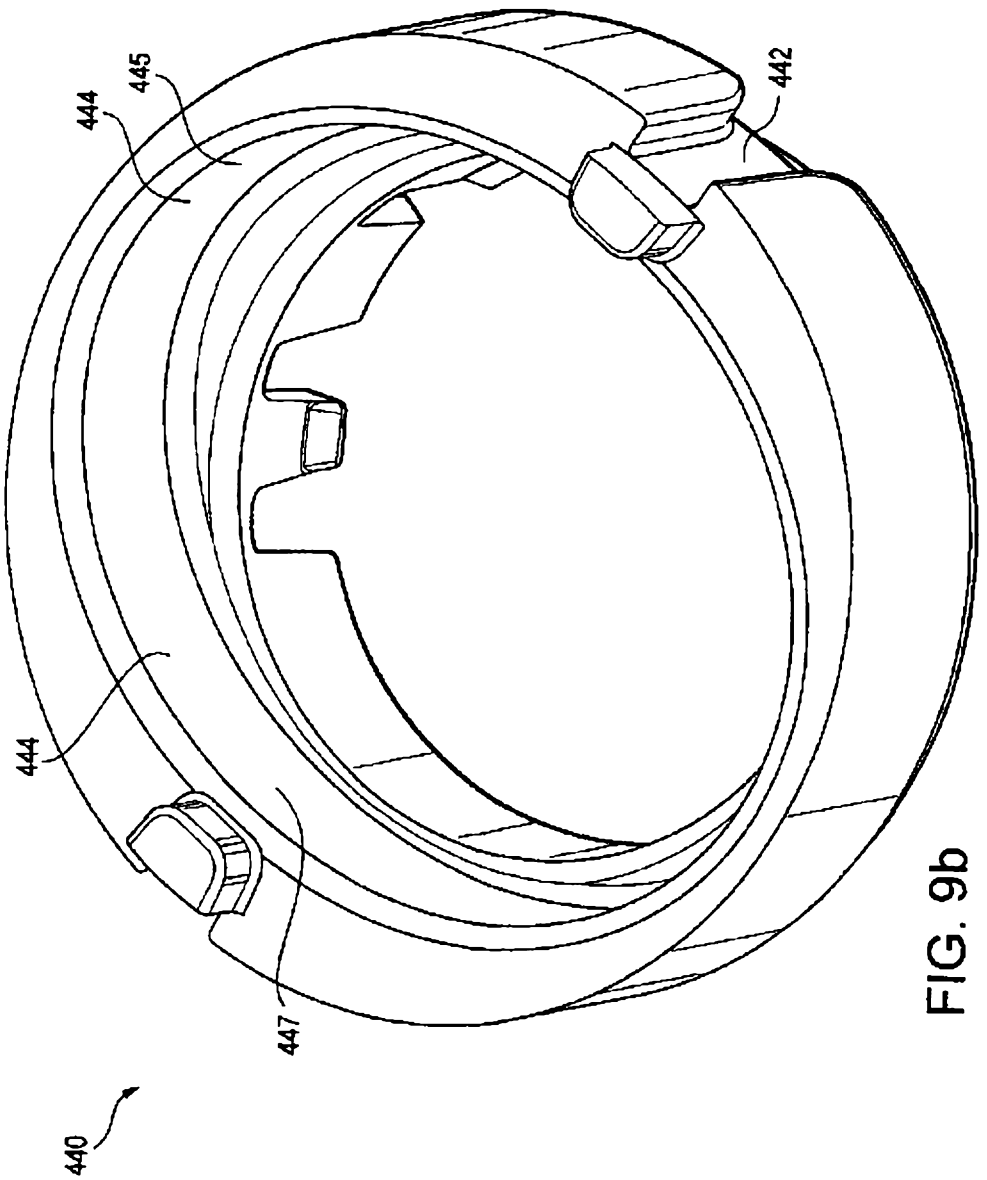

FIG. 9b

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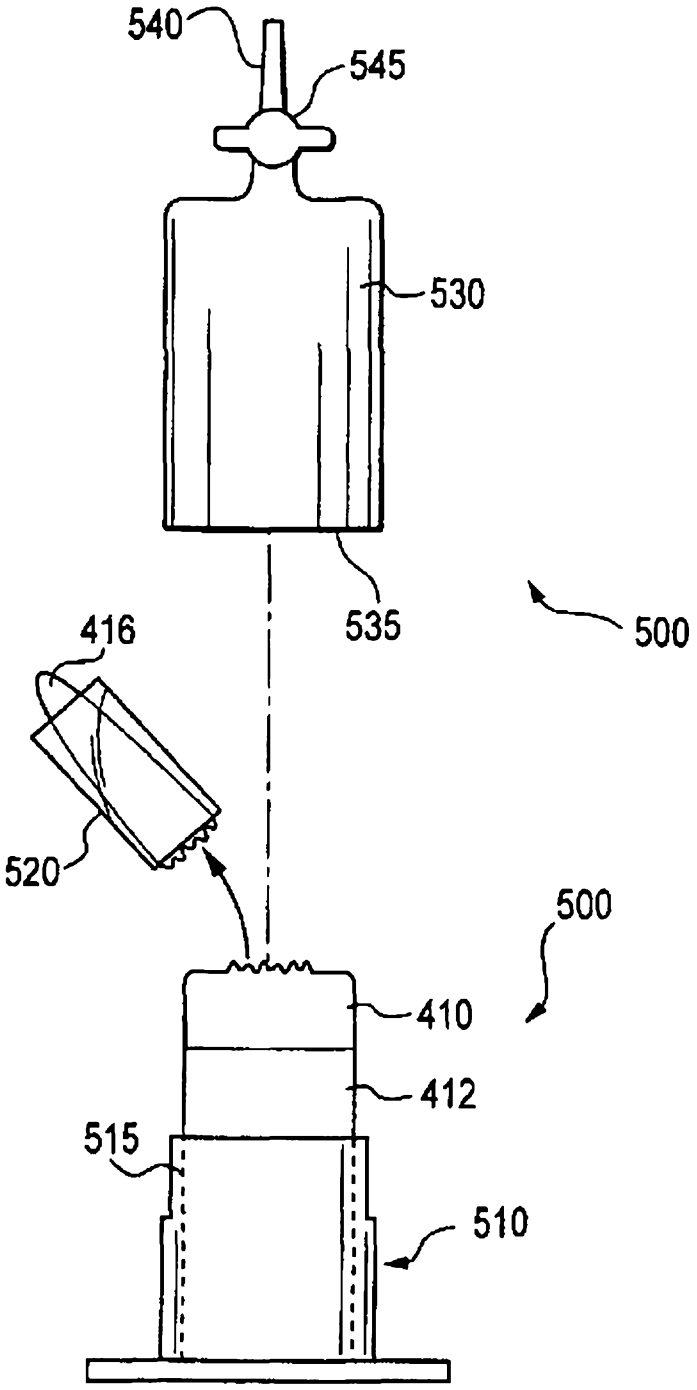

FIG. 10