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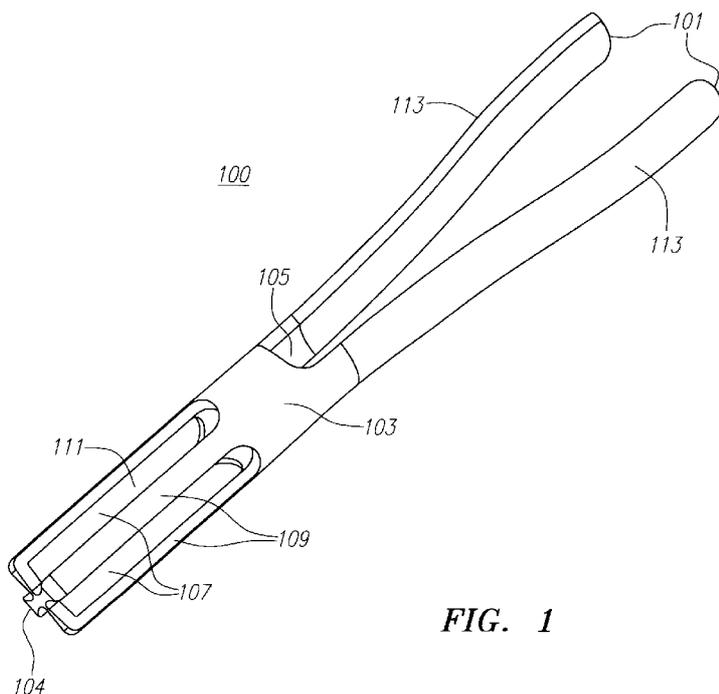


FIG. 1

(57) **Abstract:** The present invention provides devices and methods for mixing a formulation containing two or more constituents, such as a drug product and a diluent. The devices have a chamber for securing a container of the drug product. Various embodiments are presented. In one embodiment the device has two or more sides connected by a hinge, the two or more sides defining the chamber between them, and a handle for grasping and manipulating the device. In another embodiment the device has a housing with two or more side bars defining the chamber, the container being visible from outside the housing between the side bars and having a stopping element at the distal end, and a handle having two arms for grasping. In another embodiment the device has two members, one member having prongs extending from a base and the other member having tubes extending from a base, the prongs and tubes fitting together in a complementary fashion to form a chamber for the container within the tubes.

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MIXING TOOL

This application claims the benefit of U.S. provisional application 60/914,470, filed April 27, 2007.

5

Technical Field

Tools for mixing drug formulations

Background of the Invention

The preparation of a drug formulation for injection often requires
10 the user to mix a drug with a diluent immediately prior to injection. This
mixing step is a requirement for drugs known to have a relatively short
shelf life in solution. For example, a drug comprising microspheres
generally requires mixing with a diluent before administration. The dry
microspheres of the drug are initially contained in a sealed vial, and the
15 diluent is transferred from a syringe to the vial via an adaptor, which acts
as a coupler between the syringe and the vial. With the diluent and
microspheres in the vial, the user is directed to shake the syringe/vial
adaptor/vial assembly (e.g., for approximately thirty seconds) to
resuspend the microspheres in the diluent. The drug formulation can
20 then be collected by syringe in the assembly and administered
subcutaneously via a needle injection.

The mixing step is a critical step in the drug preparation that can
be difficult for some patients to execute properly or efficiently.
Generally, the syringe, vial adaptor, and vial are individually sealed but
25 packaged together in a kit. Once the patient puts the syringe/vial
adaptor/vial assembly together, the components cannot be separated
until the product is mixed. Removing any of the components from the
assembly prior to shaking exposes the contents of the vial to the
ambient surrounding. Additionally, the assembly process creates a
30 permanent hole in the vial seal through which the vial contents can leak

out. The sealed assembly can be difficult to handle, and the duration and vigorousness of the shaking required for mixing can be difficult for some patients, especially those with arthritis or limited mobility/strength in their hands and arms. Furthermore, because the vial in the assembly typically constitutes one or more effective doses of the drug, a vial mistakenly dropped or damaged during the mixing step can be very costly to the user.

A variety of mixing devices for drug/diluent formulations have been proposed to facilitate the mixing of a drug and diluent in a sealed, sterile environment. One type of device utilizes a dual-compartment syringe. One compartment of the syringe contains the diluent, and the other compartment contains the drug. The sidewall of the syringe contains a groove just forward of the stopper between the chambers. As a plunger is pushed through the syringe, the groove allows fluid to leak into the drug chamber. The drug and diluent are combined as the fluid from the diluent chamber enters the drug chamber, and then the injection is administered. The disadvantages of this method include use of a non-custom syringe and an often insufficient physical mixing of the drug and diluent.

Another device utilizes a "bottomless vial" concept for mixing drugs with diluents before administration. This concept requires the drug manufacturer to place a drug inside a bottomless vial. A second bottomless vial filled with a liquid diluent is connected adjacent to the bottomless vial containing the drug. By creating pressure in the liquid diluent vial with a plunger, the fluid is transferred into the drug vial. The plunger is then disconnected from the diluent vial and re-attached to the vial now containing drug and diluent. A needle is also attached to the drug/diluent vial and after mixing, an injection is administered. The disadvantages of this method include the use of non-custom vials, a possible exposure of the drug/diluent to the environment, and manipulation steps which may be burdensome to some users.

Summary of the Invention

The present invention provides devices and methods for mixing a formulation containing two or more constituents, such as a drug composition and a diluent to solubilize the drug for injection into a patient. The constituents can also be two or more liquids, or a combination of liquids and solids or semi-solid materials (e.g., a lyophilized product), etc.. Other aspects of the invention provide methods for mixing two constituents using a device.

In one embodiment the present invention provides a device for mixing a formulation. The device has two or more sides that are connected by a hinge and having an open position and a closed position, the two or more sides defining a chamber between them for securing a container when the sides are in the closed position. When the device is in the open position a container can be placed into the chamber. The device also has a handle connected to at least one of the two or more sides for manipulation of the device after insertion of the container. In one embodiment the device has a container present within the chamber. The container can be a vial containing a drug and/or a diluent, and a syringe can be present inserted into the vial. In one embodiment the chamber has an opening, or an at least partially transparent portion, through which the container is visible from the exterior of the device. The chamber can be sized and shaped to secure the container. By "sized and shaped" is meant that the chamber has dimensions that conform to the shape of the container contemplated for use with the device. When a container is placed in a chamber that is "sized and shaped" to the container, the container lies in the chamber securely and does not substantially move within the chamber. The container can be a vial. By "vial" is meant a small closed or sealable vessel for containing a composition. The composition can be in any form, for example a powder, crystal, liquid, or semi-liquid. In one embodiment the composition is a constituent of a drug product. The

drug product can be a composition for injection into a patient. By "secure" the container is meant that when the container is in the chamber and the device is in the closed position, the container does not substantially move in response to manipulation of the device. Rather the motion of the device is translated into movement of the composition within the container. In one embodiment the movement of the container within the chamber is less than or equal to 2 mm when the device is manipulated. In other embodiments the movement of the container within the chamber is less than 3 mm or 5 mm when the device is manipulated. In one embodiment a syringe is a standard medical use syringe for injecting formulations into a patient, and the syringe has a needle for piercing the skin, a lumen for storing formulation for injection, and a plunger for expelling formulation from the lumen of the syringe.

In one embodiment the two or more sides are two opposing sides movable about the hinge from the open to the closed position. In one embodiment the hinge separates the two sides at an angle of up to 180 degrees. The chamber can be sized and shaped to accommodate a vial having a stopper to prevent the spilling of liquids from the vial, and/or an adaptor. The two or more sides can also be present as trays for securing the container in the device. The adaptor allows the insertion and connection of a syringe to the vial so that liquid can pass from the syringe to the vial without leakage of liquid. The container can be a vial and the chamber can be sized and shaped to secure the container and the syringe.

In another aspect the invention provides a device having a housing with two or more side bars defining a chamber for securing a container inside. The container can be visible from outside the housing between two side rails of the device. The chamber has a proximal and a distal end, and a stopping element at the distal end and is open on the proximal end. The stopping element provides a distal end of the chamber and prevents the container from being inserted any further into

the chamber. The device can also have a handle comprising two arms that are connected to the chamber on the open end. The container can be inserted into the chamber through the open end between the two arms. In one embodiment the device has a container within the
5 chamber. In other embodiments the container can be a vial containing a drug product. A syringe having a plunger can be inserted into the vial. The plunger of the syringe can extend from the open and proximal end of the chamber. In one embodiment the device has a housing with four side bars. But in other embodiments the housing has three side bars, or
10 has two side bars that are of sufficient width to retain the container within the chamber. In other embodiments the housing has more than four side bars. In one embodiment the side bars lie parallel to each other. In one embodiment of the device the container is visible within the chamber between two or more of the side bars.

15 In another aspect the invention provides a device having a first member and a second member, the first member containing two or more prongs extending from a base on the first member and the second member containing two or more tubes extending from a base on the second member. The device has a first open position where the two
20 members are separated, and a second closed position where the prongs and tubes are fitted together in a complementary fashion to form a chamber within for securing a container. The tubes can define the lateral boundaries of the chamber. In one embodiment the container is a vial, which can also have an inserted syringe having a plunger for
25 expelling material from the syringe. The plunger of the syringe can protrude from an end of the device when the container and syringe are present in the chamber and the device is in the closed position. In one embodiment the container is visible between the tubes of the device when the device is in the second position. The chamber can be
30 substantially tubular in shape.

In another embodiment when the device is in the second closed position the prongs abut against the base of the second member, and the tubes abut against the base of the first member.

In another aspect the present invention provides methods of mixing a formulation. The methods involve placing the formulation into a container, inserting the container into a device as described above, placing the device into the closed position, and shaking the device to mix the formulation. In one embodiment the placing the formulation into the container involves injecting a diluent into the container with a syringe.

In another aspect the invention provides methods of preparing a formulation. The methods involve placing the formulation into a container, inserting the container into a device as described above, and shaking the device to prepare the formulation.

Description of the Drawings

Figure 1 exhibits a device according to one embodiment of the invention.

Figure 2 exhibits a device according to one embodiment of the invention.

Figure 3 exhibits a device according to one embodiment of the invention.

Figure 4 exhibits a device according to one embodiment of the invention.

Figure 5 exhibits a component of a device according to one embodiment of the invention.

Figure 6 exhibits a component of a device according to one embodiment of the invention.

Detailed Description of the Invention

Embodiments of the present invention provide a device that addresses the difficulty users have during the preparation of an active agent for administration. Embodiments generally provide a tool for
5 facilitating the mixing of a formulation containing two or more components, such as a drug with a diluent, two liquids, a liquid and a solid or semi-solid material (e.g., a lyophilized product), or combinations thereof. In one embodiment, the device facilitates the resuspension of microspheres in a diluent. Embodiments of the invention also generally
10 provide an ergonomic handle to facilitate a shaking motion of the device by the user.

Generally, embodiments of the invention provide a device comprising a chamber and a handle connected to the chamber. In
15 embodiments, the chamber comprises a housing having walls that define a lumen. In one embodiment, the chamber consists of a tubular lumen, or a lumen with a circular or elliptical cross-section. In other embodiments, the chamber is tubular for a portion of its length. Embodiments include a stopping element at one end of the chamber. In
20 embodiments, the chamber is open on the end opposite to the end with the stopping element, such that a container is capable of being inserted into the chamber through the open end. The stopping element includes any member connected to the chamber that is capable of stopping a container from passing through the chamber past the stopping element at a stopping point. In one embodiment, the stopping element can be a
25 polymer cap affixed to one end of the chamber. In another embodiment, the stopping element can be one or more protruding members extending into the chamber lumen. In yet another embodiment, the stopping element can be provided by a tapered chamber lumen with a smaller inner diameter at the stopping point than the inner diameter at the open
30 end.

A handle is capable of being connected to or integrated with the chamber in some embodiments of the invention. One embodiment consists of an ergonomic handle comprising first and second opposing surfaces. In such an embodiment, at least one of the opposing surfaces is movable from a first position to a second position in which the first opposing surface is brought closer to the second opposing surface. The handle can be constructed with similar materials which comprise the chamber, but is not limited to materials used in the construction of the chamber. In embodiments, at least a portion of the handle is movable from a first position to a second position such that the open end of the attachable chamber remains open when the handle is in a first position, and the container inserted in the chamber is capable of being restrained when the handle is in a second position. In one embodiment, a container inserted in the chamber is restrained when the opposing surfaces are moved to a position parallel to the longitudinal axis of the housing. In another embodiment, the opposing surfaces of the handle can be reversibly locked when moved from a first position to a second position. In such an embodiment, the handle may be locked using a clamp. Another embodiment would allow a user to release tension from the handle and still restrain a container in the chamber of the device. To prevent accidental dropping, embodiments of the device may also include a wrist wrap to secure the grip of a user holding the handle. Furthermore, in various embodiments, the handle can include features such as ribs to assist with handling. Additionally, in other embodiments the handle can have a contour which conforms the fingers of a human hand to further assist with handling.

The devices provided by embodiments of the present invention secure and restrain the syringe/vial adaptor/vial apparatus within the mixing tool. The vial, and hence its contents, is generally positioned within the mixing tool such that it is exposed to the maximum amount of mixing motion. In one embodiment, a vial containing a mixture of diluent

and microspheres is physically located in a chamber at a distal end of the mixing tool. The distal end of the device is exposed to the largest momentum changes when shaking the tool, thus facilitating mixing of the microspheres and diluent.

5 The device of the present invention may be manufactured by plastic injection molding as a continuous body or as individual parts which can be assembled. In some embodiments, the device can be manufactured as a packaging unit for a drug and diluent which can be opened and closed in a clamshell configuration. In such embodiments,
10 the device may be constructed using any suitable manufacturing methodology, such as vacuum thermoforming to create a continuous body capable of holding an pre-packaged apparatus comprising a vial with one or more drugs, a vial adapter, and a syringe with a diluent. These embodiments could be made from a semi-transparent material,
15 such as PETG, that would allow adequate visibility of the tray contents while the tray is in the closed configuration. In another embodiment, the housing of the device comprises a cage consisting of a tubular lumen and one or more sliding members for at least a portion of its length. The cage in this embodiment can serve as a housing for a vial-syringe
20 assembly. In such an embodiment, a handle comprising a sleeve can be configured to slide over the cage. The handle can slide over a portion of the cage and become reversibly locked. In another embodiment, the handle can comprise a tube which is configured to slide onto the housing, which comprises a tubular lumen of a smaller
25 diameter than the lumen of the handle. Other embodiments can include a chamber lumen designed to hold pens, other reconstitution containers, or various configurations of vial/vial adapter/syringe combinations.

In another embodiment, the device comprises a composite housing having a first section and a second section fitting together in a
30 complementary fashion to form a chamber for containing a container-syringe assembly. The housing sections can be affixed together in a

closed configuration by a pin and hole arrangement, by snap-fitting, or by other suitable mechanisms known in the art. In one aspect, the chamber is tubular, optionally, with a larger cross section at one end than another to form a gripping section. When the device is in a closed configuration, a user can grip the gripping section.

Embodiments of the invention also provide methods for using the described devices to physically mix two compositions such as a drug and a diluent. In one embodiment, an apparatus containing a drug and diluent is placed and secured within the mixing tool. A user then grabs the handle, and shakes the mixing tool, causing the apparatus with drug and diluent to be shaken simultaneously and consistently. The device of the present invention can be used in any delivery system that requires handling of an apparatus consisting of two or more compositions to be physically mixed. Embodiments may be used to physically mix two compositions such as two liquids, a liquid and a solid or a semi-solid material, or a liquid and a lyophilized product. In one embodiment, the invention provides a method for mixing a first solution with a second solution or with a solid or semi-solid material, comprising inserting a container comprising the first solution and the second solution or solid or semi-solid material in a device comprising a chamber and handle, restraining the container in the chamber by moving the handle to the second position holding the handle after moving the handle to the second position; and shaking the apparatus in the chamber by shaking the handle. Some embodiments of the device may be capable of being held without the presence of a handle. In such embodiments, a user is capable of holding a distal end of the device away from the inserted container comprising the first solution and second solution, solid, or semi-solid material.

Figure 1 provides an illustration of an embodiment of the present invention. In this embodiment the device includes a housing 103. The device contains a chamber 111 for securing a container inside.

Sidebars **109** define the space of the chamber **111**. When the container is present in the chamber **111** it is visible from the exterior of the device through the space **107** between the sidebars **109**. The device contains an open end **105** and a stopping element **104** that supports the
5 container in the chamber and stops it from being further introduced into the chamber. The housing **103** is rigidly connected to a handle **101** that has two arms **113**. The container is inserted into the device through the open end **105** located between the two arms **113**. In the embodiment depicted the device contains four sidebars **109**.

10 Figure 2 provides an illustration of an embodiment of the device of the invention showing a side view. There is visibly the housing **103** and window **107** allowing viewing of the chamber **111**. The stopping element **104** is also visible, and the open end **105**. In this Figure is shown a pre-packaged apparatus consisting of a syringe **201**, having a
15 plunger **209**, and a vial adapter **203**, and a vial **205** is inserted into the housing **103**. When both arms of the handle are compressed according to a direction **207**, the syringe **201**, vial adapter **203**, and vial **205** are restrained in the housing **103**. In different embodiments, the housing **103** has a diameter of about 0.25 inches to about 0.75 inches, and the
20 walls of the housing **103** have a thickness of about 0.1 inches to about 0.3 inches. In one embodiment, the diameter of the housing **103** is 0.5 inches, and the walls of the housing **103** have a thickness of 0.125 inches. Also in various embodiments the length of the device **200** can be from about 3.5 inches to about 15 inches. In one embodiment, the
25 length of the device **200** is about 10 inches.

With reference to **Figure 3** there is depicted an embodiment of the device **300** of the invention. The device **300** includes two or more sides **303** that are connected by a hinge **309**. The device is depicted in an open position. In the closed position the sides **303** define a chamber
30 **311** between them for securing a container, such as a vial. The device also contains a handle **305** that is easy to grasp when the device is in

the closed position. In this embodiment the side of the device pivots 180° about the hinge **309** to form an enclosed chamber in a closed configuration. In this depiction a container is present within the chamber **311** as a pre-packaged apparatus consisting of a syringe **201** having a plunger **209**, a vial adapter **203**, and a vial **205**. When the device **300** is moved to the closed position, the syringe **201**, vial adapter **203**, and vial **205** are secured within the housing **301**. In one embodiment, the handle **305** in a closed configuration can be used to store components accompanying a vial/syringe assembly, such as gauze, pre-packaged needles, or other materials useful for the operation of the device or use of the composition present in the container.

Figure 4 depicts a cross-sectional view of the device in the closed position. The device has a handle **305** that is easy to grasp when the device is in the closed position. There is depicted within the device a pre-packaged apparatus consisting of a syringe **201**, a vial adapter **203**, and a vial **205** secured within the housing **301**. In one embodiment the diameter of the housing **301** is approximately 0.5 inches, the diameter of the handle **305** is approximately 1.5 inches, and the length of the device **401** is approximately 10 inches. In the closed configuration of some embodiments, the handle **305** comprises a cylindrical cavity with a diameter of from approximately 1 inch to approximately 3 inches, and a length of from approximately 2 inches to approximately 5 inches. The device has a length of from approximately 3.5 inches to approximately 15 inches in some embodiments. In one embodiment, the length of the device is 9 inches.

With reference to **Figure 5** there is provided another embodiment of the device. In this embodiment the device has a first member **507** and a second member **509**. The first member **507** has two or more prongs **503** that extend from a base **511** on the first member. The second member **509** has two or more tubes **501** that extend from a base **513** on the second member. The device is depicted in a partially open

position. In the open position the first and second members are separated. In the second position the prongs of the first member and the tubes of the second member are fitted together in a complementary manner to form a chamber within. In such embodiment the tubes **501** 5 define the lateral boundaries of the chamber. The device is depicted with a prepackaged apparatus present within the chamber including a syringe **201** having a plunger 209, a vial adapter **203**, and a vial **205** inserted into the chamber. In the closed position the syringe **201**, vial adapter **203**, and vial **205** are secured within the chamber. In the closed 10 position the prongs abut against the base of the second member, and the tubes abut against the base of the first member. In other embodiments the closed position is configured so that the base **511** on the first member and the base **513** on the second member are drawn to within a convenient distance of one another and can be easily 15 manipulated or shaken by the user. In such embodiments the prongs may not abut against the base of the second member and the tubes may not abut against the base of the first member. In various embodiments the base on the first member and the base on the second member are drawn to within 6 inches of one another, or within 7 inches of one 20 another or within 8 inches of one another.

Figure 6 provides another view of the device according to one embodiment of the present invention. A prepackaged apparatus including a syringe **201**, a vial adapter 203, and a vial **205** is inserted into the chamber. The tubes **501** are placed on the prongs **503** such 25 that the syringe **201**, vial adapter **203**, and vial **205** are restrained within the chamber.

Embodiments for practicing the present invention have been described. It will be understood and readily apparent to the skilled artisan that many changes and modifications may be made to the 30 above-described embodiments without departing from the spirit and the scope of the present invention. The foregoing is illustrative only and that

Claims

1. A device for mixing a formulation comprising;

two or more sides that are connected by a hinge and having an open position and a closed position, the two or more sides defining a chamber between them for securing a container when the sides are in
5 the closed position;

a handle connected to at least one of the two or more sides for manipulation of the device after insertion of the container.
2. The device of claim 1, further comprising a container within
10 the chamber;

wherein the container comprises a vial containing a drug and a diluent, and wherein a syringe is inserted into the vial.
3. The device of claim 1, wherein the chamber comprises an opening or an at least partially transparent portion through which the
15 container is visible, and the chamber is sized and shaped to secure the container.
4. The device of claim 1 wherein the two or more sides
comprise two opposing sides movable about the hinge from the open to the closed position.
- 20 5. The device of claim 1 wherein the chamber is shaped to accommodate a vial having an adaptor, and a syringe inserted into the adaptor.
6. The device of claim 2 wherein the container is a vial and the chamber is sized and shaped to secure the container and the syringe.
- 25 7. A device comprising:

a housing comprising two or more side bars defining a chamber for securing a container inside, the container visible from outside the housing between two side bars;

the chamber having a stopping element at one end and being
5 open on the opposite end;

a handle comprising two arms and connected to the chamber on the open end, the container insertable into the chamber between the two arms.

8. The device of claim 7 further comprising a container within
10 the chamber;

wherein the container comprises a vial containing a drug and wherein a syringe comprising a plunger is inserted into the vial, the plunger of the syringe extending from the open end of the chamber.

9. The device of claim 7 wherein the housing comprises four
15 side bars.

10. The device of claim 9 wherein the container is visible within the chamber between the side bars.

11. A device comprising

a first member and a second member, the first member
20 containing two or more prongs extending from a base on the first member and the second member containing two or more tubes extending from a base on the second member,

the device comprising a first open position where the two members are separated, and a second closed position where the prongs
25 and tubes are fitted together in a complementary manner to form a chamber for securing a container, the tubes comprising the lateral boundaries of the chamber.

12. The device of claim 11 comprising a container in the chamber, said container is a vial and further comprises a syringe with a plunger,

the syringe inserted into the vial, and

5 wherein the plunger of the syringe protrudes from an end of the device when the container and syringe are present in the chamber and the device is in the closed position.

13. The device of claim 11 further wherein the container is a vial and is present inside the chamber, the vial further comprising a syringe
10 inserted into the vial.

14. The device of claim 11 wherein the container is visible between the tubes of the device when the device is in the second position.

15 15. The device of claim 11 wherein the chamber is substantially tubular.

16. The device of claim 11 wherein, when the device is in the second closed position the prongs abut against the base of the second member, and the tubes abut against the base of the first member.

17. A method of mixing a formulation comprising:
20 placing the formulation into a container;
inserting the container into a device comprising

two or more sides that are connected by a hinge and having an open position and a closed position, the two or more sides defining a chamber between them for securing a container
25 when the sides are in the closed position;

a handle connected to at least one of the two or more sides for manipulation of the device after insertion of the container.

placing the device into the closed position;

5 shaking the device to mix the formulation.

18. The method of claim 17 wherein placing the formulation into the container comprises injecting a diluent into the container with a syringe.

19. A method of preparing a formulation comprising

10 placing the formulation into a container;

inserting the container into a device comprising a housing comprising

15 two or more side bars defining a chamber for securing a container inside, the container visible from outside the housing between two side rails;

the chamber having a stopping element at one end and being open on the opposite end; a handle comprising two arms and connected to the chamber on the open end, the container insertable into the chamber between the two arms; and

20 shaking the device to prepare the formulation.

20. The method of claim 19 wherein placing the formulation in the container comprises injecting a diluent into the container with a syringe.

21. A method of preparing a formulation comprising

25 placing the formulation into a container;

inserting the container into a device comprising

a first member and a second member, the first member containing two or more prongs extending from a base on the first member and the second member containing two or more tubes extending from a base on the second member;

5 the device comprising a first open position where the two members are separated, and a second closed position where the prongs and tubes are fitted together in a complementary fashion to form a chamber for securing a container, the tubes comprising the lateral boundaries of the chamber; and

10 shaking the device to prepare the formulation,

22. The method of claim 21 wherein placing the formulation into the container comprises injecting a diluent into the container with a syringe.

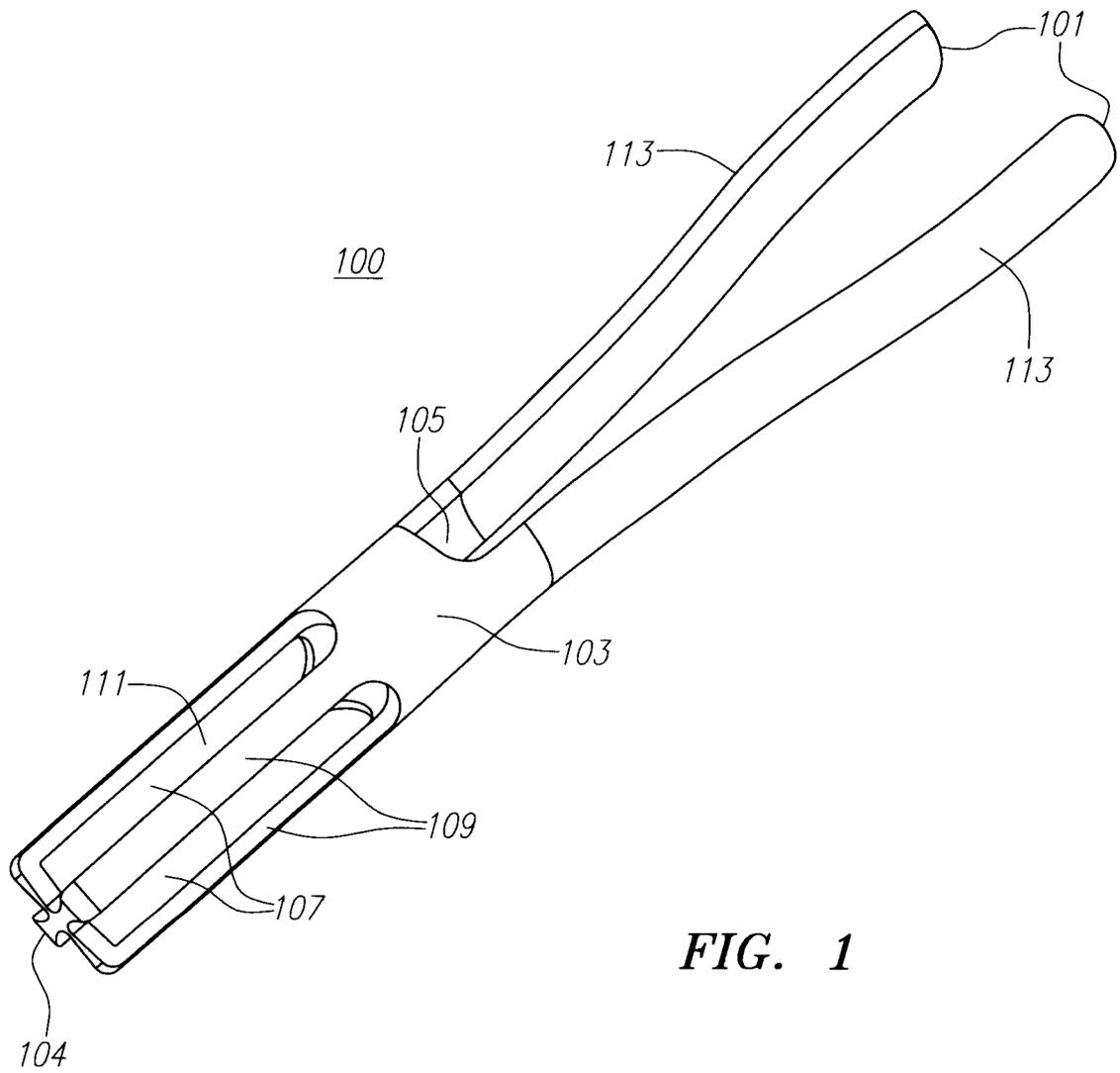


FIG. 1

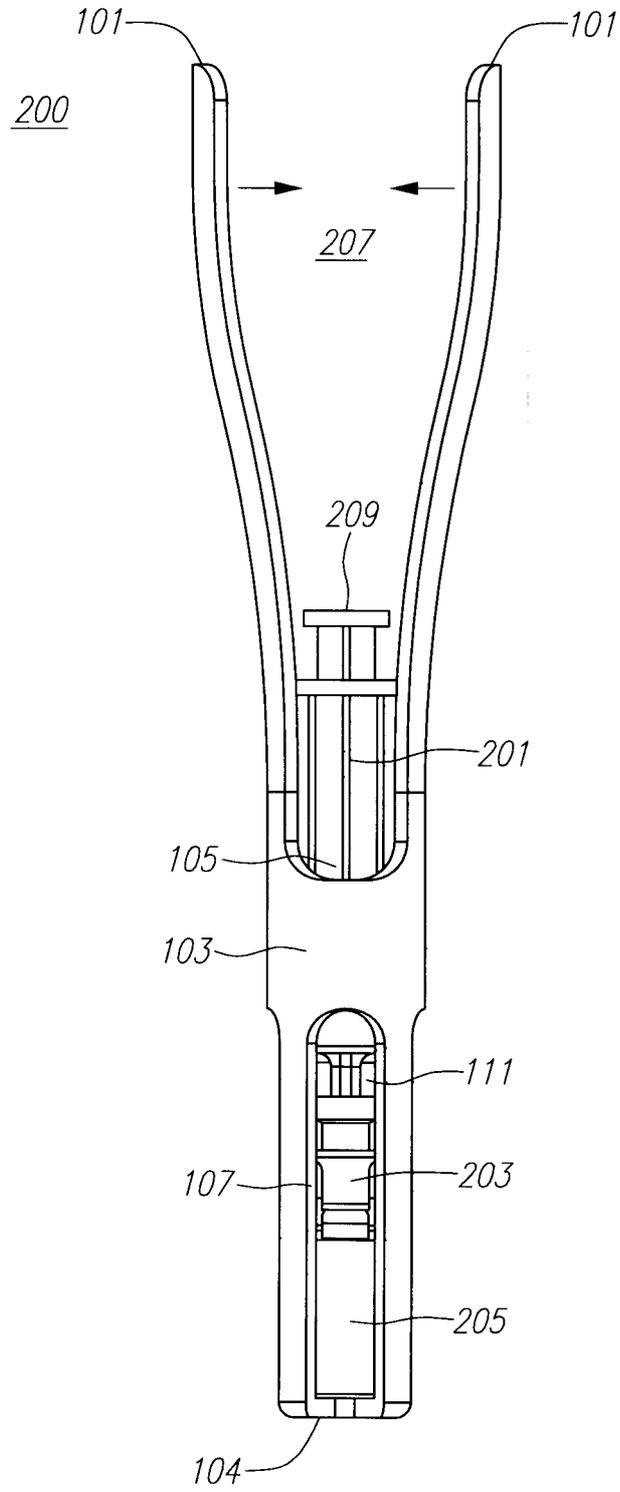


FIG. 2

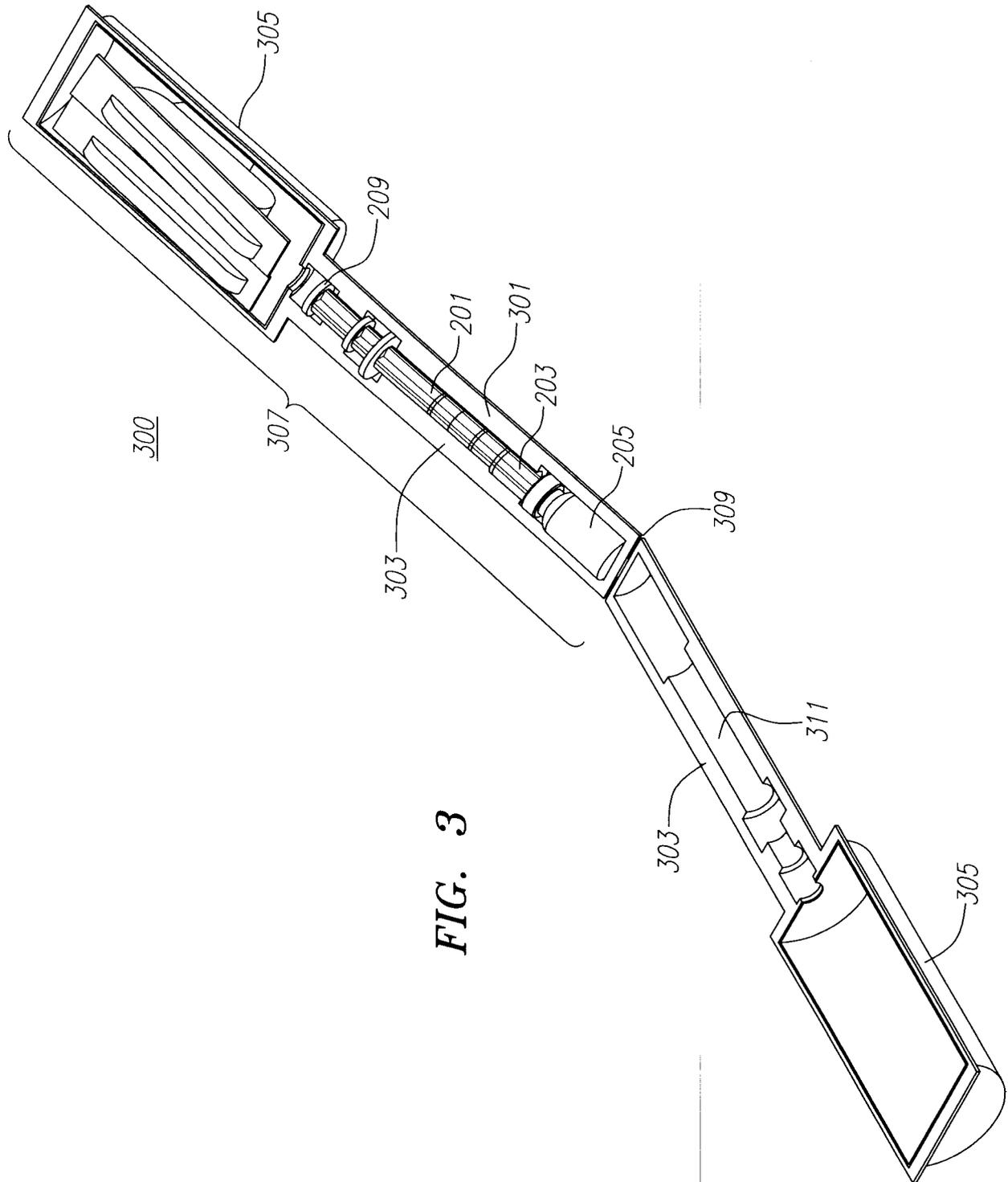


FIG. 3

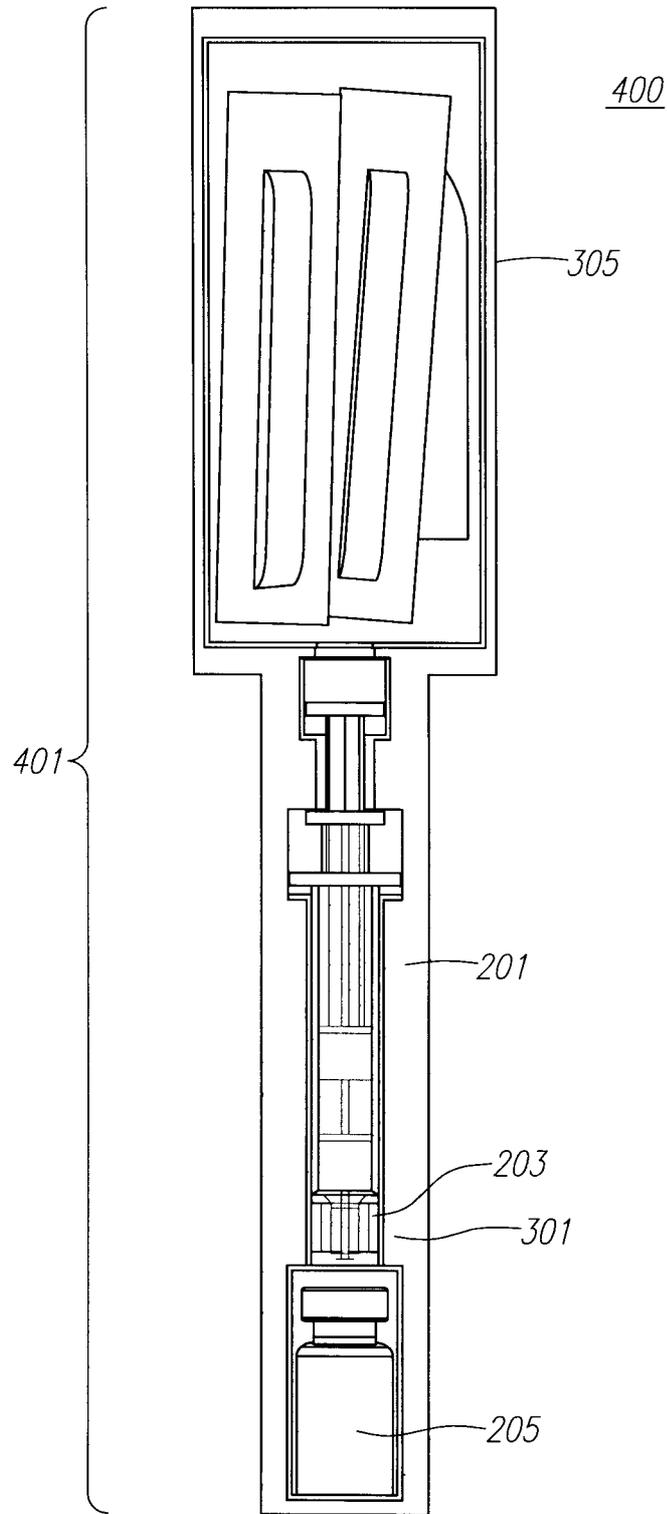


FIG. 4

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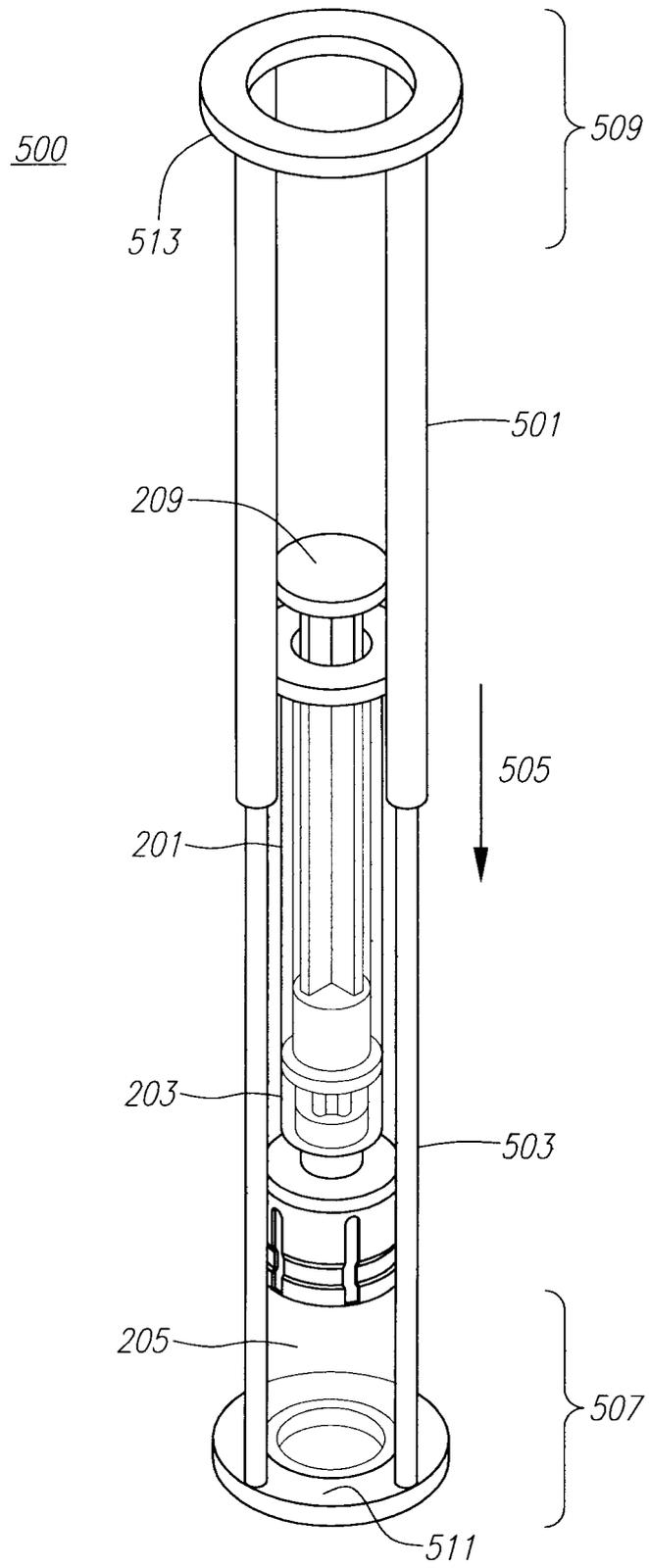


FIG. 5

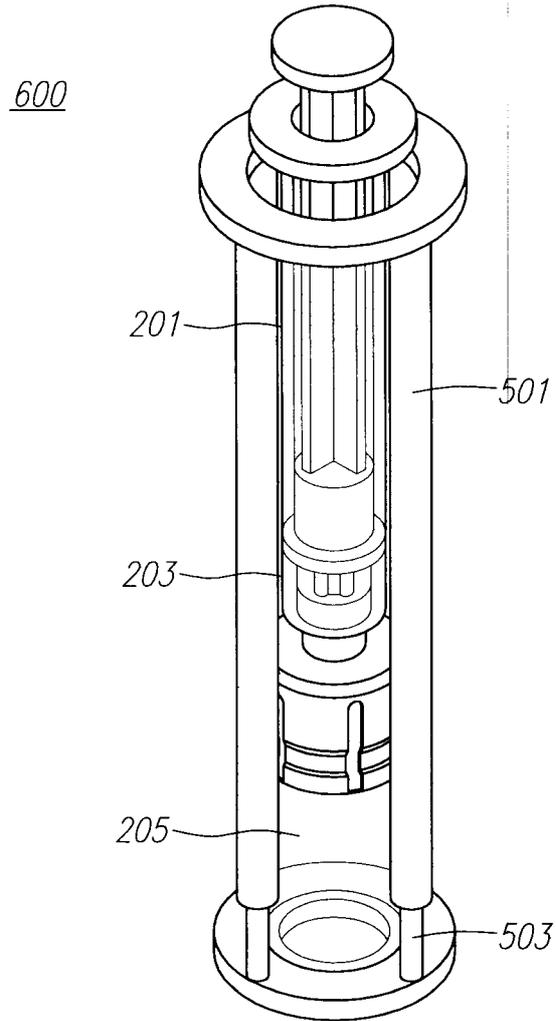


FIG. 6