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(54) Title: DEVICE FOR THE PROVISION OF BONE CEMENT

(57) **Abrégé/Abstract:**

The invention relates to a method for the production of a bone cement from at least two starting components in a device comprising a first hollow cylinder-shaped container and a second hollow cylinder-shaped container, a vessel arranged in the first container, whereby a monomer liquid is stored in said vessel. The invention also relates to a device for the provision of a bone cement from two starting components, comprising a hollow cylinder-shaped first container, in which a vessel for a monomer liquid as first starting component can be stored, a hollow cylinder-shaped second container comprising a first internal space, in which a bone cement powder as second starting component can be stored, and a second internal space into which the monomer liquid can be conveyed, a fluid-conducting conveying means arranged between the first internal space and the second internal space, whereby the first container and the second container are axially connected to each other.

## Abstract

The invention relates to a method for the production of a bone cement from at least two  
5 starting components in a device comprising a first hollow cylinder-shaped container and a  
second hollow cylinder-shaped container, a vessel arranged in the first container, whereby a  
monomer liquid is stored in said vessel. The invention also relates to a device for the  
provision of a bone cement from two starting components, comprising a hollow cylinder-  
shaped first container, in which a vessel for a monomer liquid as first starting component can  
10 be stored, a hollow cylinder-shaped second container comprising a first internal space, in  
which a bone cement powder as second starting component can be stored, and a second  
internal space into which the monomer liquid can be conveyed, a fluid-conducting conveying  
means arranged between the first internal space and the second internal space, whereby the  
first container and the second container are axially connected to each other.

## Device for the provision of bone cement

### Description

The invention relates to a method for the production of a bone cement from at least two starting components in a device comprising a first hollow cylinder-shaped container and a second hollow cylinder-shaped container, a vessel arranged in the first container, whereby a monomer liquid is stored in said vessel. The invention also relates to a device for the provision of a bone cement from two starting components, comprising a hollow cylinder-shaped first container, in which a vessel for a monomer liquid as first starting component can be stored, a hollow cylinder-shaped second container comprising a first internal space, in which a bone cement powder as second starting component can be stored, and a second internal space into which the monomer liquid can be conveyed, a fluid-conducting conveying means arranged between the first internal space and the second internal space, whereby the first container and the second container are axially connected to each other.

### 15 Background of the invention

Considerable effort is being undertaken to devise devices and methods for the provision of bone cement by means of which the bone cement thereof can be provided easily, safely, and rapidly. One important aspect of the provision of bone cement is the prevention of air inclusions in the bone cement. To prevent these, a large number of vacuum cementing systems have been described of which the following shall be listed for exemplary purposes: US 6,033,105 A, US 5,624,184 A, US 4,671,263 A, US 4,973,168 A, US 5,100,241 A, WO 99/67015 A1, EP 1020167 A2, US 5,586,821 A, EP 1016452 A2, DE 3640279 A1, WO 94/26403 A1, EP 1005901 A2, EP 1886647 A1, US 5,344,232 A.

There is a desire in the market to simplify the provision of bone cement. One advanced development is the development of cementing systems, in which both starting components are stored in separate areas of the mixing systems and are mixed with each other in the cement system only immediately prior to the cementing application. Said closed, so-called full-prepacked systems, are specified in the following specifications: EP 0692229 A1, DE 10



2009 031 178 B3, US 5,997,544 A, US 6,709,149 B1, DE 698 12 726 T2, EP 0796653 A2,  
US 5,588,745 A.

DE 10 2016 121 607 A1 describes a full-prepack system, whereby the monomer liquid-filled container is stored axially behind the bone cement. It is disadvantageous that the monomer  
5 liquid-filled container needs to be destroyed completely in the course of the mixing of the starting components. It has also been evident to be a disadvantage that the input of force, in order to mix the starting components and later on to dispense the mixed bone cement, always acts on the fragments of the destroyed container as well. This leads to an increased physical effort for the user and to jerky and uncontrollable motions both during the  
10 destruction of the containers and during the mixing and later dispensing of the mixed cement. Both of these significantly complicate the applicability of the full-prepack system, in particular in the course of time-critical operation conditions. It has been evident to be just as disadvantageous that the destroyed container complicates the use of the full pre-pack system. This is related, for example, to fragments of the container that retain monomer liquid  
15 which is then not available for production of the bone cement. Another disadvantage arises from the fragments of the container wedging inside the mixing and dispensing device. Another disadvantage is the hazard potential of the fragments both for the user and for the patients.

## 20 Objects

It is an object of the present invention to overcome, at least in part, one or more of the disadvantages resulting according to the prior art.

Specifically, the invention is based on the goal to provide devices for the provision of a bone cement from two starting components, which require a lesser exertion of force by the user  
25 than previous cementing systems, which, in addition, are easy to handle and safe to use. It is another goal to minimise the infection hazard for the patient. The devices should be well-suited for storing the two starting components separate from each other. It should be possible to combine the two starting components in the closed device within a few seconds. The device is to provide the bone cement without any mechanical mixing of the starting

components. Moreover, the device is to be designed appropriately such that the user does not have to perform any assembly steps. The device is to be capable of providing the bone cement without a vacuum being applied from outside. The device is to be capable of dispensing the bone cement thus provided. The device is to be capable of dispensing the bone cement thus provided without any conversion measures. The device is to provide and dispense the bone cement without conversion measures and without external apparatuses, such as, for example, hoses, vacuum sources or extrusion devices. The device shall be operated by as few working steps as possible in order to minimise user-related error sources.

It is another object of the invention to provide a method by means of which a bone cement made of two starting components can be provided, by means of which at least a part of the objects described above can be solved at least in part.

#### Preferred embodiments of the invention

The features of the independent claims make a contribution to meeting, at least partially, at least one of the objects specified above. The dependent claims are preferred embodiments that contribute to meeting, at least partially, at least one of the objects.

[1] Method for the production of a bone cement from at least two starting components in a device comprising

a first hollow cylinder-shaped container and a second hollow cylinder-shaped container,

a vessel arranged in the first container, whereby a monomer liquid is stored in said vessel

characterised by the steps of:

a. opening the vessel through a first motion of the vessel relative to the second container;

b. conveying the monomer liquid into a bone cement powder that is stored in a first internal space of the second container through a first axial shift of the first container into the second container; and

5 c. extruding the bone cement produced from the monomer liquid and the bone cement powder from the device by means of a second axial shift of the first container into the second container.

[2] Method according to embodiment 1, characterised in that the vessel is pressed onto an opening device arranged in the first container in order to open the vessel according to step a).

10 [3] Method according to embodiment 2, characterised in that the vessel is pressed onto the opening device by means of a conveying plunger that is arranged in the first container in order to open the vessel according to step a).

15 [4] Method according to any one of the preceding embodiments, characterised in that a screw-type means is arranged on the first container and acts on the conveying plunger in a force-locking and/or form-fitting manner in order to press the vessel onto the opening device in the course of the first motion.

[5] Method according to any one of the preceding embodiments, characterised in that, after opening the vessel, the monomer liquid flows into a second internal space in the second container.

20 [6] Method according to any one of the preceding embodiments, characterised in that the first container comprises a dispensing plunger that is moved into the second internal space during the first shift.

25 [7] Method according to any one of the preceding embodiments, characterised in that the dispensing plunger conveys the monomer liquid into the bone cement powder during the first shift and extrudes the bone cement from the device during the second shift.

[8] Device for the provision of a bone cement from two starting components, including



a hollow cylinder-shaped first container, in which a vessel for a monomer liquid as first starting component can be stored;

5 a hollow cylinder-shaped second container comprising a first internal space, in which a bone cement powder as second starting component can be stored, and a second internal space, into which the monomer liquid can be conveyed;

a fluid-conducting conveying means arranged between the first and the second internal space;

whereby the first container and the second container are axially connected to each other;

10 characterised by

an opening means being arranged in the first container in order to open the vessel during a first motion of the vessel relative to the second container;

whereby the first container can be axially shifted into the second container in appropriate manner in order to

15 a. convey the monomer liquid from the second internal space into the first internal space during a first shift;

b. convey the bone cement produced from the monomer liquid and the bone cement powder from the device during a second shift.

20 |9| Device according to embodiment 8, characterised in that the first container comprises an opening device in order to open the vessel and allow the monomer liquid to flow out.

25 |10| Device according to embodiment 8 or 9, characterised in that the first container comprises an axially shiftable conveying plunger that acts on the vessel in force-locking and/or form-fitting manner in order to press the vessel onto the opening device through a first motion of the vessel.

- [11] Device according to any one of the embodiments 8 to 10, characterised in that a screw-type means is arranged on the first container in order to shift the conveying plunger axially, in particular in that the screw-type means is arranged on a first end of the first container.
- 5 [12] Device according to embodiment 11, characterised in that the screw-type means is designed in the form of a handle that embraces the first container, at least in part, in bonnet-like manner, in particular in that an internal thread is arranged in the bonnet-like embracement.
- 10 [13] Device according to embodiment 12, characterised in that at least parts of an external surface of the first container comprise an external thread that acts in concert with the internal thread of the bonnet-like embracement in force-locking and/or form-fitting manner.
- 15 [14] Device according to any one of the embodiments 8 to 13, characterised in that a second end of the first container projects into the second container in the way of a plunger.
- [15] Device according to embodiment 14, characterised in that the second end of the first container is connected to a dispensing plunger in force-locking and/or form-fitting and/or firmly bonded manner.
- 20 [16] Device according to any one of the embodiments 8 to 15, characterised in that a first end of the second container comprises an internal thread.
- [17] Device according to embodiment 16, characterised in that, for a second shift, the internal thread of the second container acts in concert with the external thread of the first container in force-locking and/or form-fitting manner in order to convey the bone cement.
- 25 [18] Device according to embodiment 17, characterised in that a threaded sleeve is arranged between the internal thread and the external thread in order to form a coaxial double pair of threads.



## General Information

Ranges specified in the present description include the values specified as the limits. A specification of “in the range of X to Y” with regards to a parameter A therefore means that A can assume values X, Y, and values between X and Y. Accordingly, ranges of a parameter A limited on one side in the way of “up to Y” include values equal to Y and less than Y.

## Detailed description of the invention

A first subject matter of the invention relates to a method for the production of a bone cement from at least two starting components in a device comprising a first hollow cylinder-shaped container and a second hollow cylinder-shaped container, a vessel arranged in the first container, whereby a monomer liquid is stored in said vessel, characterised by the steps of.

- a. opening the vessel through a first motion of the vessel relative to the second container;
- b. conveying the monomer liquid into a bone cement powder that is stored in a first internal space of the second container through a first axial shift of the first container into the second container; and
- c. extruding the bone cement produced from the monomer liquid and the bone cement powder from the device by means of a second axial shift of the first container into the second container.

Since the vessel filled with the monomer liquid is stored inside the first container and the first container conveys both the monomer liquid and later the bone cement in the course of the method by means of being inserted into the second container, there is no need to fully destroy the vessel. Accordingly, the method allows for the vessel having to be opened in a spot only. Consequently, the user has to expend less force and the conveyance of the monomer liquid into the first internal space proceeds well-controlled, since no fragments of the vessel are situated in the displacement pathway of the dispensing plunger. Moreover, there is less risk of fragments of the vessel becoming wedged during the use of the device. Likewise, the injury risk from fragments is lowered both for the patient and the user.

Moreover, no conversion measures on the device and no external apparatuses, such as, for example, pumps or hoses, are needed in the further course of the method. In addition to the advantages of opening the vessel in just a spot as described above, this ensures that the method takes place in a simple, safe and rapid manner. Both the conveying of the monomer liquid and the dispensation of the bone cement are effected in sequence with a similar shift. This ensures that the user cannot confuse steps of the method. Rather, the sequence of the individual steps is predetermined by the device.

One embodiment of the method according to the invention is characterised in that the vessel is pressed onto an opening device arranged in the first container in order to open it according to step a). According to the invention, an opening device shall be understood to be a device that is suitable for destroying the structural integrity of the vessel and for opening it in the process. According to the invention, the embodiment of the opening device shall be selected as a function of the structural stability of the vessel. According to the invention, the material of the opening device is suitable for destruction of the structural integrity of the material of the vessel. It is advantageous for the opening device to have a small diameter as compared to the surface of the vessel to be opened. This reduces the force expenditure required for opening the vessel. For example, the vessel can be opened by puncturing or cutting into it. Examples of opening devices comprise puncturing mandrels, needles, cannulas, and cutting edges.

In a preferred embodiment, the vessel is a glass ampoule and the opening device is a puncturing mandrel. The puncturing mandrel is advantageous in that it can open the glass ampoule in a spot, while leaving the rest of the ampoule intact. In a further preferred embodiment, the vessel is a glass ampoule and the opening device is a puncturing mandrel arranged appropriately such that the puncturing mandrel opens an ampoule base of the glass ampoule. A typical glass ampoule comprises an ampoule body, an ampoule head, and an ampoule base. The ampoule head is characterised by having a small diameter as compared to the ampoule body, which serves as a predetermined breakage site. It is customary to open the glass ampoule at the predetermined breakage site. Typically, the ampoule base has the same diameter as the ampoule body. It is advantageous according to the invention to break open the glass ampoule at the ampoule base. Firstly, using a puncturing mandrel to puncture the ampoule base, the glass ampoule is opened in a more



controlled fashion due to the large difference in surface area between the opening device and the ampoule base. Secondly, the ampoule head being opened does not break off the remaining ampoule body, which reduces both the expenditure of force for opening and the number of fragments.

5 A further embodiment of the method according to the invention is characterised in that the vessel is pressed onto the opening device by means of a conveying plunger that is arranged in the first container in order to open it according to step a). According to the invention, a conveying plunger shall be understood to be an axially mobile component that can press the vessel onto the opening device and thus open it through a targeted axial shift within the first  
10 container. According to the invention, the vessel is situated between the opening device and the conveying plunger. The conveying plunger can take a variety of shapes on the side facing the vessel. For example, the conveying plunger can be flat or can be shaped as a shoulder element. If the vessel is an ampoule, preferably a glass ampoule, the conveying plunger is preferred to be shaped as a shoulder element. As described above, it is  
15 advantageous to open the glass ampoule at the ampoule base. Accordingly, the ampoule head points in the direction of the conveying plunger. A shoulder element is preferred, since the shoulder element attaches on the ampoule base rather than the ampoule head. The shoulder element is designed appropriately in this context such that contact takes place only with a shoulder, but not with the ampoule head of the vessel. In this context, the shoulder  
20 element is designed to be tubular, whereby the diameter of the hollow space is appropriate such that the ampoule head, but not the shoulder of the vessel, can be taken up into the shoulder element. Accordingly, the shoulder element protects the ampoule head from breaking off inadvertently. As a result, the force applied by the conveying plunger does not act on the predetermined breakage site and the ampoule head remains on the ampoule  
25 body, resulting in the advantages described above.

Another embodiment of the method according to the invention is characterised in that a screw-type means is arranged on the first container and acts on the conveying plunger in a force-locking and/or form-fitting manner in order to press the vessel onto the opening device in the course of the first motion. Preferably, the screw-type means can be designed in the  
30 form of a handle such that the input of force can be made more easily by the user. In an embodiment, the screw-type means can comprise an internal thread and the first container



can comprise an external thread, whereby the threads engage in form-fitting and/or force-locking manner in order to shift the vessel onto the opening device by means of the conveying plunger.

5 A further embodiment of the method according to the invention is characterised in that, after opening the vessel, the monomer liquid flows into a second internal space in the second container. For this purpose, the opened vessel is held such that the first container is situated at a higher spatial level than the second container. By this means, the method according to the invention minimises possible error sources and user errors since it is only necessary to open the vessel and to hold the device according to the orientation described above in order  
10 to convey the monomer liquid into the second internal space. No additional conversion measure or additional working step, such as, for example, the actuation of a lever, is required.

A further embodiment of the method according to the invention is characterised in that the first container comprises a dispensing plunger that is moved into the second internal space  
15 during the first shift. In a preferred embodiment, the dispensing plunger is arranged between first container and second internal space. This allows for a direct action of force, not on the vessel, but on the monomer liquid that is conveyed into the second internal space through an axial shift of the dispensing plunger. As a result, as described above, the vessel does not need to be destroyed completely after the vessel is opened and the monomer liquid flows  
20 out.

A further embodiment of the method according to the invention is characterised in that the dispensing plunger conveys the monomer liquid into the bone cement powder during the first shift and extrudes the bone cement from the device during the second shift. As a result of the spatial positioning of the dispensing plunger between the first container and the second  
25 internal space, the dispensing plunger, in concert with the container wall, needs to be designed initially permeable to gases and liquids for the monomer liquid to be able to access the second internal space. Subsequently, the dispensing plunger needs to be designed impermeable to liquids and solids since, unless this is the case, the monomer liquid cannot be conveyed from the second internal space into the first internal space. According to the  
30 invention, the dispensing plunger undergoes a transformation from being permeable to gases and liquids to being impermeable to liquids and solids in the course of the use of the device.

According to the invention, a position of the dispensing plunger shall be understood to be a state of the dispensing plunger or a spatial arrangement of the dispensing plunger in the second container.

5 In an embodiment, the dispensing plunger, in the first position, comprises at least one opening that permits the exchange of gases and liquids between the first container and the second internal space. Accordingly, the at least one opening is closed to liquid and solid matter in the second position of the dispensing plunger. For example, the dispensing plunger in the first position can comprise at least one opening that can be closed by rotating the dispensing plunger about the longitudinal axis of the dispensing plunger into the second  
10 position such that no further exchange takes place.

A second subject matter of the present invention relates to a device for the provision of a bone cement from two starting components, comprising a hollow cylinder-shaped first container, in which a vessel for a monomer liquid as first starting component can be stored, a hollow cylinder-shaped second container comprising a first internal space, in which a bone  
15 cement powder as second starting component can be stored, and a second internal space into which the monomer liquid can be conveyed, a fluid-conducting conveying means arranged between the first internal space and the second internal space, whereby the first container and the second container are axially connected to each other, characterised by an opening means being arranged in the first container in order to open the vessel during a first  
20 motion of the vessel relative to the second container, whereby the first container can be axially shifted into the second container in appropriate manner in order to

- a. convey the monomer liquid from the second internal space into the first internal space during a first shift;
- b. convey the bone cement produced from the monomer liquid and the bone cement  
25 powder from the device during a second shift.

A further embodiment of the device according to the invention is characterised in that the first container comprises an opening device in order to open the vessel and allow the monomer liquid to flow out.



A further embodiment of the device according to the invention is characterised in that the first container comprises an axially shiftable conveying plunger that acts on the vessel in force-locking and/or form-fitting manner in order to press the vessel onto the opening device through a first motion of the vessel.

5 A further embodiment of the device according to the invention is characterised in that a screw-type means is arranged on the first container in order to shift the conveying plunger axially, in particular in that the screw-type means is arranged on a first end of the first container.

10 A further embodiment of the device according to the invention is characterised in that the screw-type means is designed in the form of a handle that embraces the first container, at least in part, in bonnet-like manner, in particular in that an internal thread is arranged in the bonnet-like embracement. The shaping as a handle is advantageous to the user since the force input by the user required in order to open the vessel can be made more easily.

15 A further embodiment of the device according to the invention is characterised in that at least parts of an external surface of the first container comprise an external thread that acts in concert with the internal thread of the bonnet-like embracement in force-locking and/or form-fitting manner. The threads acting in concert reduce the force input to be made by the user and thus simplifies the use of the device.

20 A further embodiment of the device according to the invention is characterised in that a second end of the first container projects into the second container like a plunger. In this context, the first container has an external diameter and the second container has an internal diameter that are matched appropriately such that the containers can be inserted into each other, at least in part. The containers are connected or can be connected to each other as one protrudes into the other. In an embodiment, at least a part of the external diameter of the  
25 first container corresponds essentially to an internal diameter of the second container such that sliding the containers into each other cannot only convey the monomer liquid from the second internal space into the first internal space, but can also convey the bone cement from the device in a later step of the method. In a further embodiment, the external diameter is smaller, at least in part, than the internal diameter such that the risk of the containers  
30 becoming wedged while being slid into each other is reduced.



A further embodiment of the device according to the invention is characterised in that the second end of the first container is connected to a dispensing plunger in force-locking and/or form-fitting and/or firmly bonded manner. According to the invention, this shall be understood to mean that the first container and the dispensing plunger are firmly connected to each other  
5 or that the first container and the dispensing plunger consist of just a single part. In an embodiment, the dispensing plunger is firmly connected to the first housing, for example by means of a screw, a nail, a clamp, a wedge or a rivet. In a further embodiment, the first container is designed appropriately such that a base surface of the first container forms the dispensing plunger. If the first container and the dispensing plunger are connected to each  
10 other in force-locking and/or form-fitting and/or firmly bonded manner, an input of force acting on the first container can be utilised directly to convey the monomer liquid from the second internal space into the first internal space. It is an advantage in this context that no additional components are required in order to effect an axial motion of the dispensing plunger, which renders the device easier and more reliable to use. It is another advantage that the input of  
15 force for shifting the dispensing plunger is applied axially onto the device, which reduces the force expended by the user.

A further embodiment of the device according to the invention is characterised in that a first end of the second container comprises an internal thread. The axial connection between first container and second container can be established by means of the internal thread.

20 A further embodiment of the device according to the invention is characterised in that, for a second shift, the internal thread of the second container acts in concert with the external thread of the first container in force-locking and/or form-fitting manner in order to convey the bone cement. In an embodiment, internal thread and external thread act in concert appropriately such that the second shift can take place in the desired direction only. This is  
25 advantageous, on the one hand, in that a user does not need to expend additional force in order to prevent the device from rotating back. On the other hand, a risk of air bubbles forming is reduced.

A further embodiment of the device according to the invention is characterised in that a threaded sleeve is arranged between the internal thread and the external thread in order to  
30 form a coaxial double pair of threads. The use of a threaded sleeve allows the first container to be designed with a smaller diameter than if no threaded sleeve was used. This reduces

the risk of first container and second container becoming wedged during the use of the device.

The method according to the invention is characterised in that it produces bone cements from two starting components. According to the invention, a bone cement shall be

5 understood to be a substance that is well-suited to provide a stable connection between artificial joints, such as, for example, hip and knee joints, and bone material in the realm of medical technology. Preferably, bone cements are polymethylmethacrylate bone cements (PMMA bone cements). PMMA bone cements have been used in medical applications for a long period of time and are based on the pioneering work of J. Charnley (cf. Charnley, J.

10 Anchorage of the femoral head prosthesis of the shaft of the femur. J. Bone Joint Surg. 1960; 42, 28-30.). In this context, PMMA bone cements can be produced from a bone cement powder as first starting component and a monomer liquid as second starting component. If the composition is appropriate, the two starting components separated from each other can be stable on storage. When the two starting components are contacted to each other, the

15 polymer components of the bone cement powder are generated by swelling forming a plastically deformable bone cement, which is also referred to as bone cement dough. A polymerisation of the monomer by radicals is initiated in this context. Upon advancing polymerisation of the monomer, the viscosity of the bone cement dough increases until the bone cement dough solidifies completely.

20 According to the invention, a bone cement dough shall be understood to be a powder, which comprises at least one particulate polymethylmethacrylate and/or one particulate polymethylmethacrylate copolymer. Examples of copolymers include styrene and/or methylacrylate. In an embodiment, the bone cement powder can comprise, in addition, a hydrophilic additive that supports the distribution of the monomer liquid within the bone

25 cement powder. In a further embodiment, the bone cement powder can comprise, in addition, an initiator that initiates the polymerisation. In a further embodiment, the bone cement powder can comprise, in addition, a radiopaquer. In yet a further embodiment, the bone cement powder can comprise, in addition, pharmaceutically active substances, such as, for example, antibiotics.

30 Preferably, the bone cement powder comprises at least one particulate polymethylmethacrylate and/or one particulate polymethylmethacrylate copolymer, an



initiator, and a radiopaquer or it consists of said components. Also preferably, the bone cement powder comprises at least one particulate polymethylmethacrylate and/or one particulate polymethylmethacrylate copolymer, an initiator, a radiopaquer, and a hydrophilic additive or it consists of said components. Most preferably, the bone cement powder  
5 comprises at least one particulate polymethylmethacrylate and/or one particulate polymethylmethacrylate copolymer, an initiator, a radiopaquer, a hydrophilic additive, and an antibiotic or it consists of said components.

According to the invention, the particle size of the particulate polymethylmethacrylate and/or of the particulate polymethylmethacrylate copolymer of the bone cement powder can  
10 correspond to the sieved fraction of less than 150  $\mu\text{m}$ , preferably of less than 100  $\mu\text{m}$ .

According to the invention, the hydrophilic additive can be particulate and/or fibrous in shape. In a further embodiment, the hydrophilic additive is poorly soluble, preferably insoluble, in methylmethacrylate. In a further embodiment, the hydrophilic additive can possess an absorption capacity of at least 0.6 g methyl methacrylate per gram of hydrophilic additive. In  
15 a further embodiment, the hydrophilic additive can comprise a chemical substance with at least one OH group. In this context, the invention can preferably provide the hydrophilic additive to possess covalently bound OH groups on its surface. Examples of said preferred hydrophilic additives can be additives selected from the group comprising cellulose, oxycellulose, starch, titanium dioxide, and silicon dioxide, whereby pyrogenic silicon dioxide  
20 is particularly preferred. In an embodiment, the particle size of the hydrophilic additive can correspond to the sieved fraction of less than 100  $\mu\text{m}$ , preferably of less than 50  $\mu\text{m}$ , and most preferably of less than 10  $\mu\text{m}$ . The hydrophilic additive can be present in an amount of up to 0.1 to 2.5 wt.%, relative to the total weight of the bone cement powder.

According to the invention, the initiator can contain dibenzoyl peroxide or consist of dibenzoyl  
25 peroxide.

According to the invention, a radiopaquer shall be understood to be a substance that allows the bone cement to be visualised on diagnostic radiographs. Examples of radiopaquers can include barium sulfate, zirconium dioxide, and calcium carbonate.



According to the invention, the pharmaceutically active substance can comprise one or more antibiotics and, if applicable, added cofactors for the one or more antibiotics. Preferably, the pharmaceutically active substance consists of one or more antibiotics and, if applicable, added cofactors for the one or more antibiotics. Examples of antibiotics include, inter alia,  
5 gentamicin, clindamycin, and vancomycin.

According to the invention, the monomer liquid can comprise the methylmethacrylate monomer or consist of methylmethacrylate. In an embodiment, the monomer liquid comprises, aside from the monomer, an activator that is dissolved therein, such as, for example, N,N-dimethyl-p-toluidine, or consist of methylmethacrylate and N,N-dimethyl-p-  
10 toluidine.

### Examples

The invention is illustrated further by examples in exemplary manner in the following. The invention shall not be limited to the examples.

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### Figures

- Fig. 1 shows a schematic drawing of a cross-section of a device for the provision of a bone cement from two starting components
- Fig. 2 shows the device from Figure 1 rotated by 90° in clockwise direction
- 20 Fig. 3 shows the device from Figure 2 while a vessel with monomer liquid is being opened
- Fig. 4 shows the device from Figure 3 while the monomer liquid is being conveyed into a first internal space
- Fig. 5 shows the device from Figure 4 while the bone cement is being formed
- 25 Fig. 6 shows the device from Figure 5 while the bone cement is being dispensed

Fig. 7 shows the device from Figure 6 after completion of the dispensation process

Fig. 8 shows a flow diagram (Method for the provision of a bone cement from two starting components)

## 5 Description of the figures

**Figure 1** shows a device 100 in a starting state. The device 100 is single-part, but made up of multiple components. The device 100 comprises a first container 200 and a second container 300. The device 100 is tube-like in shape. The first container 200 and the second container 300 are axially connected to each other. The first container 200 and the second container 300 are jointly arranged on the centre axis of the device 100. The first container 200 projects into the second container 300. The first container 200 seals the second container 300 with respect to the surroundings of the device 100.

The first container 200 possesses an external thread 240 on a part of its external surface 201. A screw-type means 231 is arranged on a first end 202 of the first container 200. The screw-type means 231 surrounds the first end 202 of the first container 200 in a bonnet-like manner. The screw-type means 231 has an internal thread 232 that acts in concert with the external thread 240 in a form-fitting and/or force-locking manner. The screw-type means 231 is shaped in the form of a handle. The shape of a handle allows the input of force for the opposite rotation of the first container 200 with respect to the second container 300 to be applied more easily by the user. The internal thread 232 is not fully rotated onto the external thread 240 such that a hollow space A 235 exists between screw-type means 231 and first container 200. A conveying plunger 230 in the form of a shoulder element is arranged on the screw-type means 231. The conveying plunger is shaped to have a cross-section shaped like an H. The conveying plunger 230 projects from the first end 202 into the first container 200. The conveying plunger 230 in the form of a shoulder element is designed appropriately such that a contact can come to exist only with a shoulder 202, but not with a head 213 of a vessel 210. In this context, the conveying plunger 230 is designed to be tubular, whereby the diameter of the hollow space is appropriate such that the head 213 of the vessel 210, but not the shoulder 212 of the vessel 210, can be taken up. Accordingly, the conveying plunger 230



protects the head 213 of the vessel 210 from breaking off in an uncontrolled manner. The conveying plunger 230 can therefore act only on the shoulder 212 of the vessel 210. The first container 200 possesses a second end 203 with an opening device 220 in the form of a puncturing mandrel.

5 A monomer liquid 211 is stored in the first container 200. The monomer liquid 211 is stored in the vessel 210 in the form of a glass ampoule in this context. The vessel 210 is preferably provided as a glass ampoule since the monomer liquid 211 can be stored hermetically sealed and sterile in a glass ampoule. The vessel 210 is further preferred to be provided as a glass ampoule, since a glass ampoule is easy to open. The vessel 210 is stored in  
10 appropriate manner between the opening device 220 and the conveying plunger 230 such that the vessel 210 cannot move freely in the first container 210. By this means, an uncontrolled motion of the vessel 210 and thus an inadvertent breakage or opening of the vessel is prevented. The vessel 210, the opening device 220, and the first container 200 form a hollow space B 236.

15 A dispensing plunger 400 is attached to an external side of the second end 203 of the first container 200. The dispensing plunger 400 is cambered on a top side 401 facing the first container. The dispensing plunger 400 is firmly connected to the first container 200. The dispensing plunger 400 is connected to the first container 200 in a form-fitting and/or force-locking manner. The dispensing plunger is connected to the second end 203 of the first  
20 vessel 200 by means of a screw-type device 410. The dispensing plunger 400 and the first vessel 200 are designed to be one-part. An external surface 420 of the dispensing plunger 400 borders on a container wall 310 of the second container 300. The dispensing plunger comprises two sealing rings 430 on the external surface 420.

The second container possesses an internal thread 302 on a first end 301. A threaded  
25 sleeve 303 with an internal thread 350 is applied to the internal thread 302. The internal thread 350 can act in concert with the external thread 240 in a form-fitting and/or force-locking manner. The threaded sleeve 303 and the internal thread 202 and the external thread 350 form a coaxial double pair of threads. The use of a threaded sleeve 303 allows the first container 200 to be designed with a smaller diameter than if no threaded sleeve 303 was  
30 used. This reduces the risk of the first container 200 and second container 300 becoming wedged during the use of the device 100. The threaded sleeve 303 prevents the first



container 200 from being pulled fully out of the second container 300, since the threaded sleeve forms an undercut for the second end 203 of the first vessel 200. The second end 203 of the first vessel 200 comprises an external diameter and the threaded sleeve 303 comprises an internal diameter, whereby the external diameter of the first end 203 is larger than the internal diameter of the threaded sleeve 303. This reduces the risk of inadvertent opening and therefore contaminating the device 100. The second container 300 possesses a first internal space 320 and a second internal space 330. A bone cement powder 321 is stored in the first internal space 320. The entire second internal space 330 is filled with the bone cement powder 321. The bone cement powder 321 is appropriately compacted in the first internal space 320 such that the bone cement powder 321 is not freely mobile. A gas is situated in the intervening spaces of the bone cement powder 321. The first internal space 320 is connected to the second internal space 330 by means of a fluid-conducting conveying means 340. The conveying means 340 is designed to be permeable to gases and liquids, but impermeable to solids, such as, for example, the bone cement powder 321. The conveying means 340 comprises two sealing rings 341 in the direction of the container wall 310.

The second internal space 330 borders, in a top section, on the dispensing plunger 400. The dispensing plunger 400 in a first position is situated at the level of a first subsection 311 of the second container 300. The first subsection 311 possesses at least one recess 312 in the container wall 310. The recess 312 extends in axial direction of the second container 300. The axial extension of the recess 312 is longer than that of the dispensing plunger 400. The recess 312 is designed appropriately such that the monomer liquid 211 can flow about the dispensing plunger 400 at the level of the first subsection 311 and can thus enter into the second internal space 330.

**Figure 2** shows the device 100 from **Figure 1** rotated by 90° in clockwise direction. The screw-type means 231 is shaped as a handle for a hand. To prevent the conveying plunger 230 from being screwed in inadvertently, a locking element 234 is attached on the external thread 240 right below the screw-type means 231. The locking element 234 blocks the external thread 240 for the screw-type means 231. With the locking element 234 applied, it is not possible to fully rotate the internal thread 232 of the screw-type means 231 onto the external thread 240. With the locking element 234 applied, the hollow space A 235 is maintained between screw-type means 231 and first container 200. Accordingly, the

conveying plunger 230 can not press the vessel 210 onto the opening device 220. With the locking element 234 applied, a hollow space B 236 is maintained between opening device 220, vessel 210, and first container 200. The locking element 234 can be pulled off perpendicular to the longitudinal axis of the device 100. The axial extension of the hollow space A 235 is appropriate such that rotating the screw-type means 231 down onto the external thread 240, and thus conveying the vessel 210 onto the opening device 220, destroys the structural integrity of the vessel 210 in a spot. The axial extension of the hollow space A 235 is short enough such that the vessel 210 is punctured only in a spot without being destroyed completely. An axial extension of the hollow space B 236 is advantageously at least equal in length to an axial extension of the hollow space A 235 since, as a result, the vessel 210 can be opened only in a spot by rotating the screw-type means 231 downward.

**Figure 3** shows, by comparison to **Figure 2**, the device 100 after removal of the locking element 234 (see **Figure 2**) and with the conveying plunger 230 rotated downward. The screw-type means 231 has been rotated fully onto the external thread 240. The screw-type means 231 was rotated onto the external thread 240 in appropriate manner such that no hollow space A 235 (see **Figure 2**) exists any longer between screw-type means 231 and external thread 240. In a first motion, the conveying plunger 230 pushed the vessel 210 onto the opening device 220 and thus opened it. The conveying plunger has pressed the vessel 210 onto the opening device 220 in appropriate manner such that no hollow space B 236 (see **Figure 2**) exists any longer between the first container 200, opening device 220, and vessel 210. The opening device destroyed the structural integrity of the vessel 210 in a spot. After the screw-type means 231 is rotated down onto the external thread 240, and thus after the vessel 210 is opened, continued opposite rotation of the first container 200 with respect to the second container 300 has no effect on the device 100. This serves to reduce safety risks related to the incorrect use of the device 100. The exclusive purpose of screwing the screw-type means 231 down onto the external thread 240 is to open the vessel 210. Further process steps need to be initiated separately. This prevents a user from not allowing the monomer liquid 211 enough time after the vessel 210 is opened to flow from the vessel 210 into the second internal space 330. The second internal space 330 is spatially arranged above the first internal space 320. The vessel 210 being opened allows the monomer liquid 211 to flow from the vessel 210 under the action of gravity. The monomer liquid 211 flows under the action of gravity through at least one feedthrough 250 in the base of the first vessel



200 in the direction of the dispensing plunger 400. The dispensing plunger in the first position is situated at the level of the first subsection 311. The monomer liquid 211 flows about the dispensing plunger 400 through the recesses 312 in the container wall 310 into the second internal space 330. The monomer liquid 211 flows about the dispensing plunger 400 by means of the recesses 312 in the first subsection 311. The second internal space 330 comprises a volume that corresponds at least to the volume of the monomer liquid 211. The second internal space 330 can take up all of the monomer liquid 211.

**Figure 4** shows, by comparison to **Figure 3**, the first container 200 being inserted into the second container 300 by means of a first axial shift. In the course of the first axial shift, the first container 200 was pushed down, in a first step, into the second container 300 over a distance that corresponds to a length of a section 241 of the first container 200 that has no external thread. The length of the section 241 is such that the dispensing plunger 400 is shifted from the level of the first subsection 311 to the level of a second subsection 315. The second subsection 315 comprises no recesses in the container wall 310. The dispensing plunger 400 separates, at the level of the second subsection 311, the second internal space 330 in fluid-impermeable manner in the direction of the first container 200. The first step serves to separate the monomer liquid 211 in the internal space 330 with respect to the first container 200 in sealed manner. The first step of the first axial shift therefore serves to reduce the safety risks related to the incorrect use of the device 100. The first step of the first axial shift makes sure that all of the monomer liquid 211 that has flown into the second internal space 330 is available for further process steps and cannot flow back into the first container 200.

After completion of the first step, the device 100 is rotated appropriately such that the first internal space 320 is spatially arranged above the second internal space 330. This is advantageous in that any subsequent conveying of the monomer liquid 211 into the first internal space 320 proceeds spatially from bottom to top. Accordingly, a gas that is present between the individual particles of the bone cement powder 321 can escape in upward direction upon the monomer liquid 211 being conveyed into the first internal space 320, which reduces the risk of air inclusions being present in the bone cement.

In a second step of the first axial shift, the external thread 240 of the first container 200 acts in concert with the internal thread 302 of the second container 300 in form-fitting and/or



force-locking manner by means of a rotation about the longitudinal axis of the device 100. In this context, said action can take place through a direct contact of the internal thread 302 with the external thread 240 or by an action of the threaded sleeve 303. The figure shows the acting in concert by means of the threaded sleeve 303. In the following, the first axial shift is continued via an opposite rotation of the first container 200 relative to the second container 300. The device 100 is designed appropriately such that the opposite rotation of the first container relative to the second container 300 can take place in the direction of the first axial shift only. The device 100 is designed appropriately such that, after the onset of the second step of the first axial shift, the first container 200 and the second container 300 can no longer be unscrewed from each other. This is advantageous, on the one hand, in that a user does not need to expend additional force in order to prevent the device 100 from rotating back. On the other hand, a risk of air bubbles forming is reduced.

Due to the first axial shift of the first container 200 into the second container 300, the dispensing plunger 400 has been shifted from the first subsection 311 into a second subsection 315 and the conveying of the monomer liquid 211 into the first internal space 320 has commenced. Continuing the first axial shift of the first container 200 into the second container 300 presses the monomer liquid from the second internal space 330 via the conveying means 340 into the bone cement powder 321 in the first internal space 320.

**Figure 5** shows the device 100 after completion of the first axial shift. The first axial shift is completed when the dispensing plunger 400 reaches the conveying means 340. The conveying means 340 having been reached is indicated to a user of the device 100 by an increased counter-pressure during the opposite rotation of the container 200 with respect to the second container 300. On the one hand, the conveying means 340 is firmly locked in the second container 300 in appropriate manner such that the bone cement powder 331 can be stored in the first internal space 320 in compacted form and such that a user experiences a noticeable counter-pressure upon completion of the first axial shift. On the other hand, the conveying means 340 is easy enough to shift in the second container 300 such that a user has no difficulty shifting the conveying means 340 during the further use of the device 100. The conveying means 340 comprises two sealing rings 341 on an external surface. The sealing rings 341 provide a compromise between firm locking and easy shifting ability of the

conveying means 340. All of the monomer liquid 211 has been conveyed into the first internal space 320. The monomer liquid 211 displaced the gas in the intervening spaces of the bone cement powder 321. The gas in the intervening spaces of the bone cement powder 321 is forced in the direction of a dispensing opening 500, which is arranged to be adjacent to the first internal space 320. The dispensing opening 500 is provided with a closing pin 501. The closing pin 501 prevents the bone cement powder 321 from being dispensed inadvertently from the device 100. The closing pin 501 is designed to be permeable to gases, and optionally also to the monomer liquid 211. The gas from the intervening spaces of the bone cement powder 321 has been expelled from the device 100 through the closure pin 501.

After completion of the first axial shift, all of the bone cement powder 321 is wetted by the monomer liquid 211. Once the bone cement powder 321 is completely wetted by the monomer liquid 211, the volume of the bone cement powder 321 expands. During the expansion of the bone cement powder 321, the closing pin 501 is expelled partially out of the dispensing opening 500. This indicates to the user that the device 100 works properly and that the bone cement powder 321 is wetted completely by the monomer liquid 211. The mixing of bone cement powder 321 and monomer liquid 211 leads to the formation of a bone cement 322. Combining bone cement powder 321 and monomer liquid 211 results in swelling of the bone cement powder 321.

**Figure 6** shows the device 100 during a second axial shift of the first container 200 into the second container 300. The closing pin 501 (see Figure 5) has been replaced by a dispensing cannula 502. The second axial shift is effected through a continued opposite rotation of the first container 200 with respect to the second container 300 about the longitudinal axis of the device 100, whereby the internal thread 350 of the threaded sleeve 303 acts in concert with the external thread 240 in a form-fitting and/or force-locking manner. During the second axial shift, the dispensing plunger 400 pushes the conveying means 340 in the direction of the dispensing opening 500. The second axial shift of the first container 200 into the second container 300 conveys the bone cement 322 from the internal space 320 out of the device 100 into the dispensing cannula 502.

**Figure 7** shows the device 100 after completion of the second axial shift of the first container 200 into the second container 300. The conveying means 340 has been pushed all the way to the base of the second container 300 by the dispensing plunger 400. The bone cement



322 has been extruded completely from the device 100. The dispensing cannula 502 affords the application of the bone cement 322 at the desired site. The dispensing cannula 502 is still filled with residual bone cement 322. Due to the first container 200 being inserted into the second container 300, the device 100 adopted a shorter axial extension. The vessel 210 is not completely destroyed after completion of the dispensation of the bone cement 322. The vessel 210 is only opened in a spot by the opening device 220 after completion of the dispensation of the bone cement 322.

**Figure 1 to Figure 7** show the device 100 during the provision and mixing of the starting components and the dispensation of the bone cement 322. A user starts by removing the locking element 234 from the external thread 240 of the first container 200. The purpose of the locking element 234 is to prevent the vessel 210 with the monomer liquid 211 from being opened inadvertently. Once the locking element 234 is removed, the user screws down the screw-type means 231, which is initially not fully rotated onto the external thread 240 of the first container 200. The screw-type means 231 acts on the conveying plunger 230 in this context such that the latter is being pushed further into the first container 200. In this regard, the conveying plunger 230 must be arranged in the first container 200 such as to be axially mobile. The screw action of the screw-type means 231 results in an axial motion of the conveying plunger 230 towards the vessel 210. In the process, the conveying plunger 230 transfers - essentially - the axial motion of the screw-type means 231 to the shoulder of the vessel 210 in order to press the latter onto the opening device 220 and to thus open it in a spot. The conveying plunger 230 serves as a transfer means of the force on the vessel 210, which is generated in the thread when the screw-type means 231 is being screwed onto the external thread 240 and is directed into the device 100. The shoulder 212 of the vessel 210 is structurally sufficiently sound such that the vessel 210 is opened adjacent to the opening device 220 only. In one variant, the screw-type means 231 can be screwed down onto the external thread 240 only to the extent such that the vessel 210 is destroyed in a spot, but not completely. Once the screw-type means 231 is rotated completely onto the external thread 240, continuing the rotary motion leads to no further axial motion of the conveying plunger 230. Only the first container 200 can then be rotated by its longitudinal axis within the device 100. If the vessel 210 is opened, the monomer liquid 211 flows from the inside of the vessel 210 in the direction of the dispensing plunger 400. As described above, the dispensing plunger 400 in the first position is permeable to the monomer liquid 211. In order to convey



the monomer liquid 211 into the second internal space 330, the device 100 is held appropriately such that the container 200 is spatially situated above the second container 300. By this means, gravity is utilised to convey the monomer liquid 211 into the second internal space 330, which is the reason why no external apparatus, such as, for example, a pump or a vacuum connection, is required. In order to provide for essentially complete transfer of the monomer liquid 211 into the second internal space 330, the device 100 can be held in the orientation described above, with the second container 300 downwards, for a period of time of 60 seconds, in particular 30 seconds, preferably 10 seconds. To prevent the monomer liquid 211 from flowing back into the first container 200 after it is conveyed into the second internal space 330, the first container 200 is pushed, at least in part, into the second container 300 by means of the first axial motion. This transfers the conveying plunger 400 from the first position into the second position. Accordingly, the monomer liquid 211 can no longer flow back through the recess 312 in the direction of the first container 200.

Subsequently, the device 100 is rotated appropriately such that the second container 300 is spatially arranged above the first container 200. This is advantageous in that the gas that is present in the second internal space 330 and between the particles of the cement powder 321 is displaced in the direction of the dispensing opening 500, when the monomer liquid 211 is subsequently conveyed from the second internal space 330 into the first internal space 320. Conducting the gas specifically in the direction of the dispensing opening 500 of the device 100 reduces the risk of gas inclusions being present within the mixed bone cement 322.

To convey the monomer liquid 211 from the second internal space 330 into the first internal space 311, a force acting on the dispensing plunger 400 in the direction of the conveying means 340 is required. For this purpose, the external thread 240 of the first container 200 acts in concert with the internal thread 302 of the second container 300. Said acting in concert can take place directly- i.e. form-fitting and/or force-locking - or, as shown, through the aid of a threaded sleeve 303. For this purpose, the user rotates the screw-type means 231 appropriately such that the external thread 240 engages the internal thread 350 of the threaded sleeve 303 and such that the first container 200 is screwed into the second container 300 by means of said rotary motion. Preferably, the screw-in process can be made to be non-reversible, which also reduces a generation of gas inclusions. A corresponding

non-return lock ensures that in the case of the conveying being interrupted, forces possibly built up in the device 100 do not increase a distance between dispensing plunger 400 and the conveying means 340, in particular dispensing opening 500.

5 The first axial shift is completed when the dispensing plunger 400 reaches, in particular touches on, the conveying means 340. At this point in time, the conveying of the monomer liquid 211 into the first internal space 320 is completed. The completion of the first axial shift is indicated to the user by means of an increased counter-pressure while rotating the screw-type means 231 and by the closing pin 502 being partially expelled.

10 Before the user initiates the second axial shift by continuing to rotate the screw-type means 231, the device remains in the above-described position in order to allow the bone cement 322 sufficient time to be produced. The period of time depends on the composition and properties of the starting materials and can be a period from 5 seconds to 5 minutes. Subsequently, the second axial shift of the first container 200 into the second container 300 is initiated. Depending on the application site of the bone cement 322, it makes sense to  
15 provide the device 100 with the dispensing cannula 502 on the dispensing opening 500 before dispensing the bone cement 322. The second axial shift is continued until the desired amount or all of the bone cement 322 has been dispensed from the device 100. The spatial orientation of the device 100 during the second axial shift can be selected arbitrarily, according to need.

20 **Figure 8** shows a flow diagram containing steps 610 to 650 of a method 600 for the provision of a bone cement from two starting components by means of the device 100 comprising the hollow cylinder-shaped first container 200, in which the monomer liquid 211 as first starting component is stored in the vessel 210, the hollow cylinder-shaped second container 300 comprising the container wall 310, the first internal space 320, and the second internal space  
25 330, whereby the bone cement powder 321 as second starting component is stored in the first internal space 320, and whereby the monomer liquid 211 can be conveyed into the second internal space 330, the fluid-conducting conveying means 340 arranged between the first internal space 320 and the second internal space 330, whereby the first container 200 and the second container 300 are axially connected to each other. In a preferred  
30 embodiment of the method 600, the vessel 210 is a glass ampoule since a glass ampoule is easy to sterilise and to destroy. In a further preferred embodiment of the method 600, the



dispensing plunger 400 is situated at the level of a first position within the second vessel 300. The first position is characterised in that the container wall 310 bordering on the dispensing plunger 400 comprises recesses 312.

5 The vessel 210 is opened in a first step 610. Preferably, the vessel 210 is opened in a spot only and is not destroyed completely. In a preferred embodiment of the method 600, the first container 200 is spatially arranged above the second container 300 before the step 610 such that the monomer liquid 211 can flow downwards in the direction of the second container 300 through the force of gravity. In a further preferred embodiment of the method 600, step 610  
10 takes place through rotating downwards the conveying plunger 230, which presses the vessel 210 onto the opening device 220 in the form of a puncturing mandrel and thus opens it in a spot.

In a second step 620, the monomer liquid 211 flows out of the vessel 210, about the dispensing plunger 400 into the second internal space 330. In a further preferred embodiment of the step 620, the monomer liquid 211 flows about the dispensing plunger 400  
15 via at least one recess 312 in the container wall 310. In a further preferred embodiment of the step 620, the monomer liquid 211 flows about the dispensing plunger 400 via recesses 312 in the form of a groove. In a preferred embodiment of the step 620, the dispensing plunger 400 is cambered in order for all of the monomer liquid 211 to be conducted in the direction of the recesses 312.

20 In a third step 630, the monomer liquid 211 is conveyed out of the second internal space 330 into the first internal space 320 through a first shift of the first container 200 into the second container 300. In a preferred embodiment of the step 630, the dispensing plunger 400 is inserted from the first position into a second position in the course of a first step. The second position is characterised in that the container wall 310 bordering on the dispensing plunger  
25 400 is designed to be free of recesses. The monomer liquid 211 cannot flow about the dispensing plunger 400 at the level of the second position. The dispensing plunger 400 seals the second internal space 330 at the level of the second position to liquids and solids with respect to the first container 200. In a further preferred embodiment of the step 630, the device 100 is rotated appropriately after the first step such that the second container 300 is  
30 spatially arranged above the first container 200. As a result, a gas present between the particles of the bone cement powder 321 can be displaced from the bone cement powder

321 by the monomer liquid 211 with less trouble, with a reduced risk of air inclusions in the further course of the method 600. In a further preferred embodiment of the step 630, the first container 200 comprises an external thread 240 and the second container 300 comprises an internal thread 302, whereby external thread 240 and internal thread 302 can act in concert  
5 in form-fitting and/or force-locking manner in order to shift the first container 200 into the second container 300. In a further preferred embodiment of the step 630, the device comprises a threaded sleeve 303. The threaded sleeve and the internal thread 302 and the external thread 240 form a coaxial double pair of threads. In a second step of the first axial shift, the external thread 240 and the internal thread 302 act in concert appropriately,  
10 preferably by means of the threaded sleeve 303, such that the first container 200 is inserted into the second container 300. The second step of the first axial shift conveys the monomer liquid 211 from the second internal space 330 into the first internal space 320.

In a fourth step 640, the production of the bone cement 322 from bone cement powder 321 and monomer liquid 211 takes place. In a preferred embodiment of the step 640, the  
15 production of the bone cement 322 starts with the bone cement powder 321 being wetted by the monomer liquid 211. Once wetted, the bone cement powder 321 swells.

In a fifth step 650, the bone cement 322 is dispensed from the device 100 through a second shift of the first container 200 into the second container 300. In a preferred embodiment of the step 650, the dispensation of the bone cement 322 from the device 100 takes place  
20 through a continued opposite rotation of the first container 200 with respect to the second container 300. In a further preferred embodiment, the vessel 210 is not fully destroyed after the dispensation of the bone cement 322. In a further preferred embodiment of the method 600, the vessel 210 is opened only in a spot after the dispensation of the bone cement 322.

It is an advantage of the method 600 according to the invention that the vessel 210 does not  
25 need to be destroyed completely while the bone cement 322 is being mixed and dispensed. Firstly, this reduces the required expenditure of force by the user, secondly the disadvantages of fragments of the vessel 210 described above are prevented. It is another advantage of the method 600 according to the invention that the substeps 630 and 650 take place in sequence with similar process steps and that there is no possibility of changing or  
30 confusing the sequence of the process steps. Accordingly, the application of the method 600 is simple, safe, and rapid.



In summary, it can be noted that the invention is characterised by a device that comprises two containers, whereby the monomer liquid is stored in the first container and the bone cement powder is stored in the second container. According to the invention, the first container is inserted into the second container, whereby the first container being inserted axially

1. opens the vessel for the monomer liquid;
2. conveys the monomer liquid into the bone cement powder; and
3. dispenses the ready-made bone cement produced from monomer liquid and bone cement powder without mixing, in the order given.

It is noted that the embodiments of the invention are described with reference to various states of facts. Specifically, some embodiments are described with reference to device claims, whereas other embodiments are described with reference to method claims. However, a person skilled in the art will interpret the aforementioned information and the description to understand, unless specified otherwise, that the present application discloses not only a combination of features belonging to one type of object, but also a combination of features relating to various objects. All features can be combined with each other, which may lead to synergy effects that exceed the simple sum of the effects of the features.

Whereas the invention has been illustrated and described in detail in the drawings and the preceding description, said figures and descriptions shall be understood to be illustrative or exemplary and in no way as restrictive. The invention shall not be limited to the disclosed embodiments. Variations of the embodiments disclosed here can be comprehended and designed by persons skilled in the art from a study of the drawings, disclosure and independent claims.

The term “comprising” in the claims shall not exclude other elements or steps. Likewise, the indefinite article “a” or “an” shall not exclude any plurality. The mere fact of certain features being quoted in claims that are independent of each other shall not indicate that a

combination of said claims could not be utilised to advantage. Any reference numbers in the claims shall not be interpreted as restrictions.



## List of reference numbers

	100	Device
	200	First container
5	201	External surface of the first container
	202	First end of the first container
	203	Second end of the first container
	210	Vessel
	211	Monomer liquid
10	212	Shoulder of the vessel
	213	Head of the vessel
	220	Opening device
	230	Conveying plunger
	231	Screw-type means
15	232	Internal thread of the screw-type means
	233	Shoulder element
	234	Locking element of the conveying plunger
	235	Hollow space A
	236	Hollow space B
20	240	External thread

- 241 Area with no external thread
- 250 Feedthroughs
- 300 Second container
- 301 First end of the second container
- 5 302 Internal thread of the second container
- 303 Threaded sleeve
- 310 Container wall
- 311 First subsection
- 312 Recess
- 10 315 Second subsection
- 320 First internal space
- 321 Bone cement powder
- 322 Bone cement
- 330 Second internal space
- 15 340 Conveying means
- 341 Sealing rings of the conveying means
- 350 Internal thread of the threaded sleeve
- 400 Dispensing plunger
- 401 Top side of the dispensing plunger
- 20 410 Screw-type device



- 420 External surface of the dispensing plunger
- 430 Sealing rings of the dispensing plunger
- 500 Dispensing opening
- 501 Closing pin
- 5 502 Dispensing cannula
- 600 Method for the provision of a bone cement
- 610 Vessel being opened
- 620 Monomer liquid flowing
- 630 First shift of the first container into the second container
- 10 640 Production of the bone cement
- 650 Second shift of the first container into the second container

## Claims

1. Method (600) for the production of a bone cement (322) made of at least two starting components in a device (100) comprising  
  
a first hollow cylinder-shaped container (200) and a second hollow cylinder-shaped container (300),  
  
a vessel (210) arranged in the first container (200), whereby a monomer liquid (211) is stored in said vessel (210);  
  
**characterised by the steps of:**
  - a. opening (610) the vessel (210) through a first motion of the vessel (210) relative to the second container (300);
  - b. conveying the monomer liquid (211) into a bone cement powder (321) that is stored in a first internal space (320) of the second container (300) through a first axial shift (630) of the first container (200) into the second container (300); and
  - c. extruding the bone cement (322) produced from the monomer liquid (211) and the bone cement powder (321) from the device (100) by means of a second axial shift (650) of the first container (200) into the second container (300).
2. Method (600) according to claim 1, **characterised in that** that the vessel (210) is pressed onto an opening device (220) arranged in the first container (200) in order to open (610) the vessel (210) according to step a).
3. Method (600) according to claim 2, **characterised in that** that the vessel (210) is pressed onto the opening device (220) by means of a conveying plunger (230) that is arranged in the first container (200) in order to open (610) the vessel (210) according to step a).



4. Method (600) according to any one of the preceding claims, **characterised in that** a screw-type means (231) is arranged on the first container (200) and acts on the conveying plunger (230) in a force-locking and/or form-fitting manner in order to press the vessel (210) onto the opening device (220) in the course of the first motion.
5. Method (600) according to any one of the preceding claims, **characterised in that**, after opening (610) the vessel (210), the monomer liquid (211) flows into a second internal space (330) in the second container (300).
6. Method (600) according to any one of the preceding claims, **characterised in that** the first container (200) comprises a dispensing plunger (400) that is moved into the second internal space (330) during the first shift (650).
7. Method (600) according to any one of the preceding claims, **characterised in that** the dispensing plunger (400) conveys the monomer liquid (211) into the bone cement powder (321) during the first shift (630) and extrudes the bone cement (322) from the device during the second shift (650).
8. Device (100) for the provision of a bone cement (322) made of two starting components, comprising
  - a hollow cylinder-shaped first container (200), in which a vessel (210) for a monomer liquid (211) as first starting component can be stored;
  - a hollow cylinder-shaped second container (300) comprising a first internal space (320), in which a bone cement powder (321) as second starting component can be stored, and a second internal space (330), into which the monomer liquid (211) can be conveyed;
  - a fluid-conducting conveying means (340) arranged between the first internal space (320) and the second internal space (330);
  - whereby the first container (200) and the second container (300) are axially connected to each other;**characterised by**

an opening means (220) being arranged in the first container (200) in order to open the vessel (210) during a first motion of the vessel (210) relative to the second container (300);

whereby the first container (200) can be axially shifted into the second container (300) in appropriate manner in order to

- a. convey the monomer liquid (211) from the second internal space (330) into the first internal space (320) during a first shift (630);
- b. convey the bone cement (322) produced from the monomer liquid (211) and the bone cement powder (321) from the device (100) during a second shift (650).

9. Device (100) according to claim 8, **characterised in that** the first container (200) comprises an opening device (220) in order to open the vessel (210) and allow the monomer liquid (211) to flow out.
10. Device (100) according to claim 8 or 9, **characterised in that** the first container (200) comprises an axially shiftable conveying plunger (230) that acts on the vessel (210) in force-locking and/or form-fitting manner in order to press the vessel (210) onto the opening device (220) through a first motion of the vessel (210).
11. Device (100) according to any one of the claims 8 to 10, **characterised in that** a screw-type means (231) is arranged on the first container (200) in order to shift the conveying plunger (230) axially, in particular in that the screw-type means (231) is arranged on a first end (202) of the first container (200).
12. Device (100) according to claim 11, **characterised in that** the screw-type means (231) is designed in the form of a handle that embraces the first container (200), at least in part, in bonnet-like manner, in particular in that an internal thread (232) is arranged in the bonnet-like embracement.
13. Device according to claim 12, **characterised in that** at least parts of an external surface of the first container (200) comprise an external thread (240) that acts in



concert with the internal thread (232 of the bonnet-like embracement in force-locking and/or form-fitting manner.

14. Device (100) according to any one of the claims 8 to 13, **characterised in that** a second end (203) of the first container (200) projects into the second container (300) in the way of a plunger.
15. Device (100) according to claim 14, **characterised in that** the second end (203) of the first container (200) is connected to a dispensing plunger (400) in force-locking and/or form-fitting and/or firmly bonded manner.
16. Device (100) according to any one of the claims 8 to 15, **characterised in that** a first end (301) of the second container (300) comprises an internal thread (302).
17. Device (100) according to claim 16, **characterised in that**, for a second shift (650), the internal thread (302) of the second container (300) acts in concert with the external thread (240) of the first container (200) in force-locking and/or form-fitting manner in order to convey the bone cement (322).
18. Device (100) according to claim 17, **characterised in that** a threaded sleeve (303) is arranged between the internal thread (302) and the external thread (240) in order to form a coaxial double pair of threads.

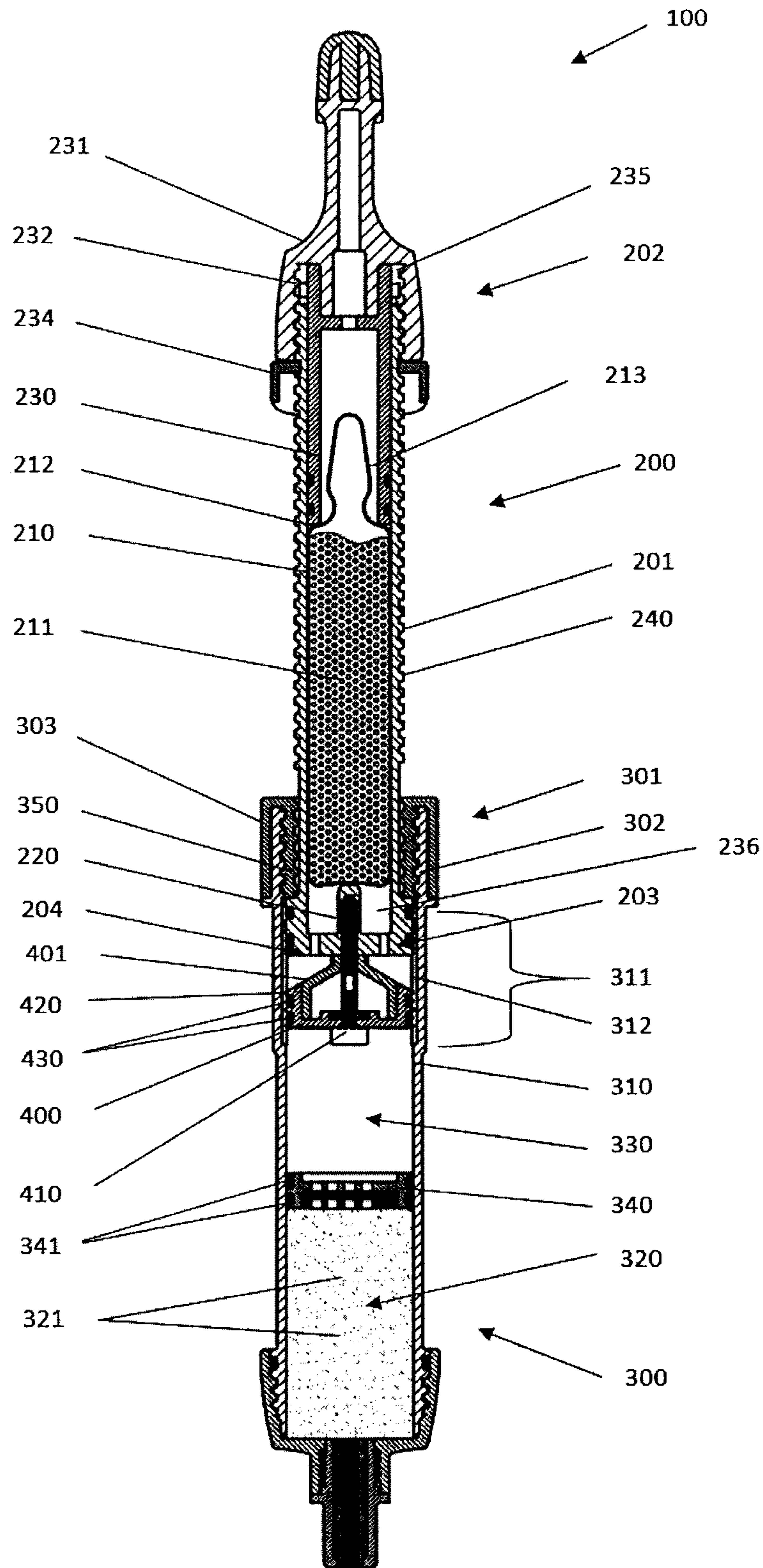


Fig. 1



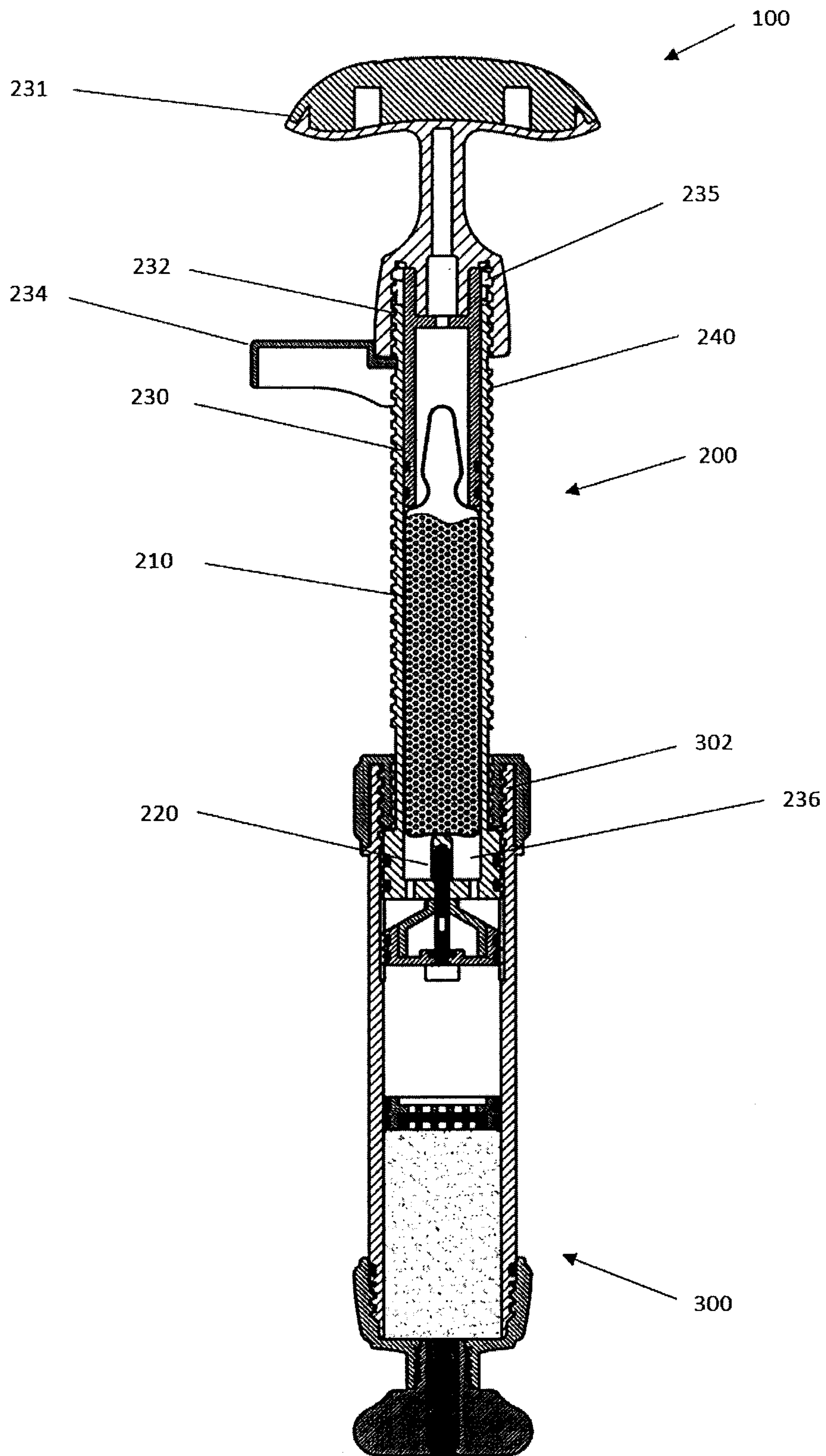


Fig. 2

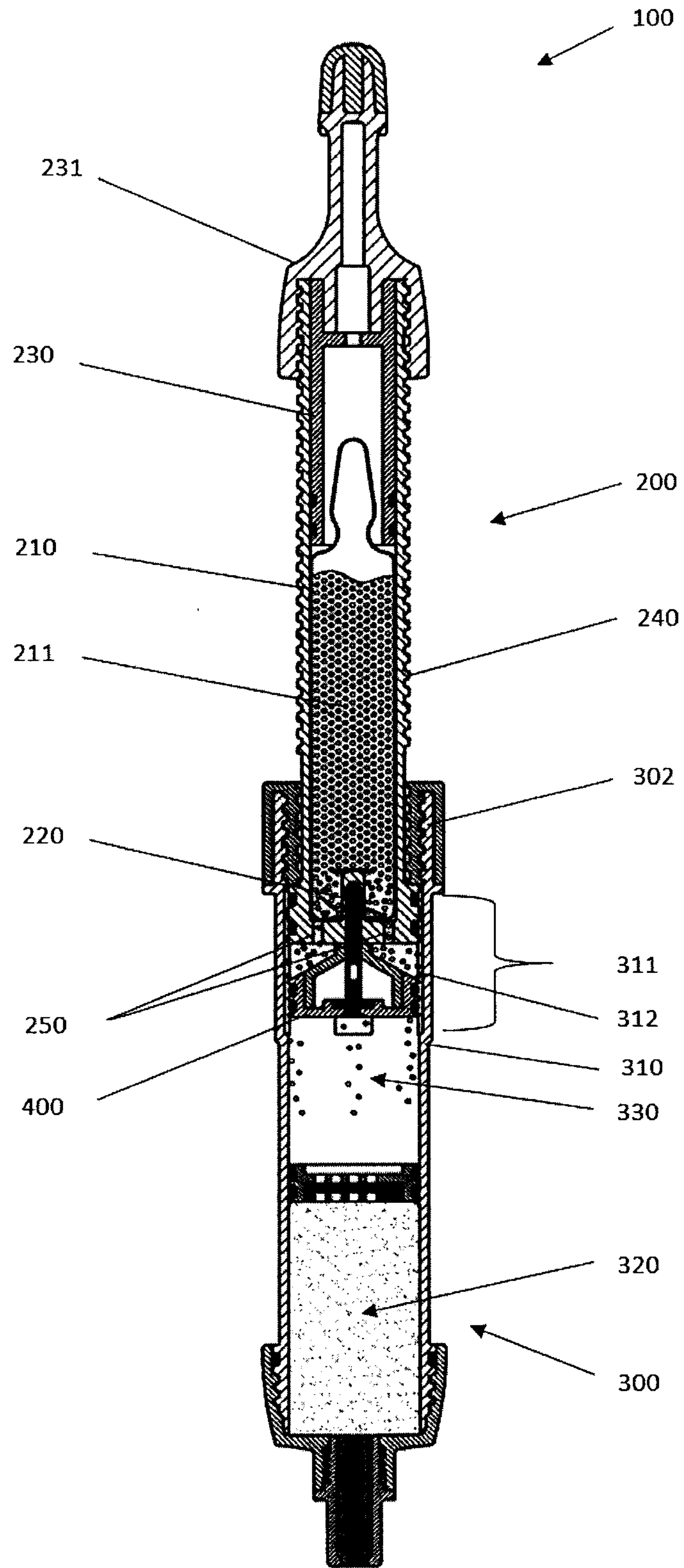


Fig. 3



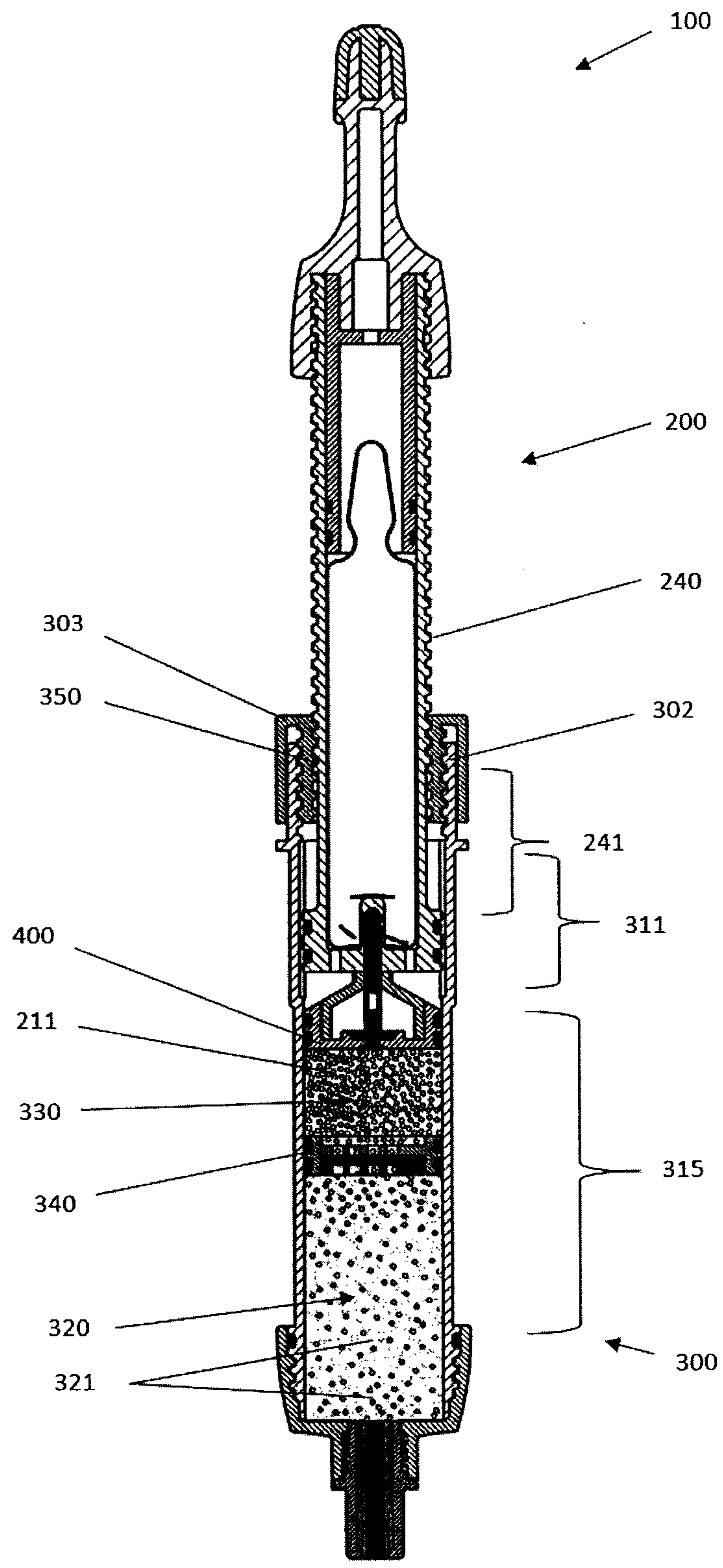


Fig. 4

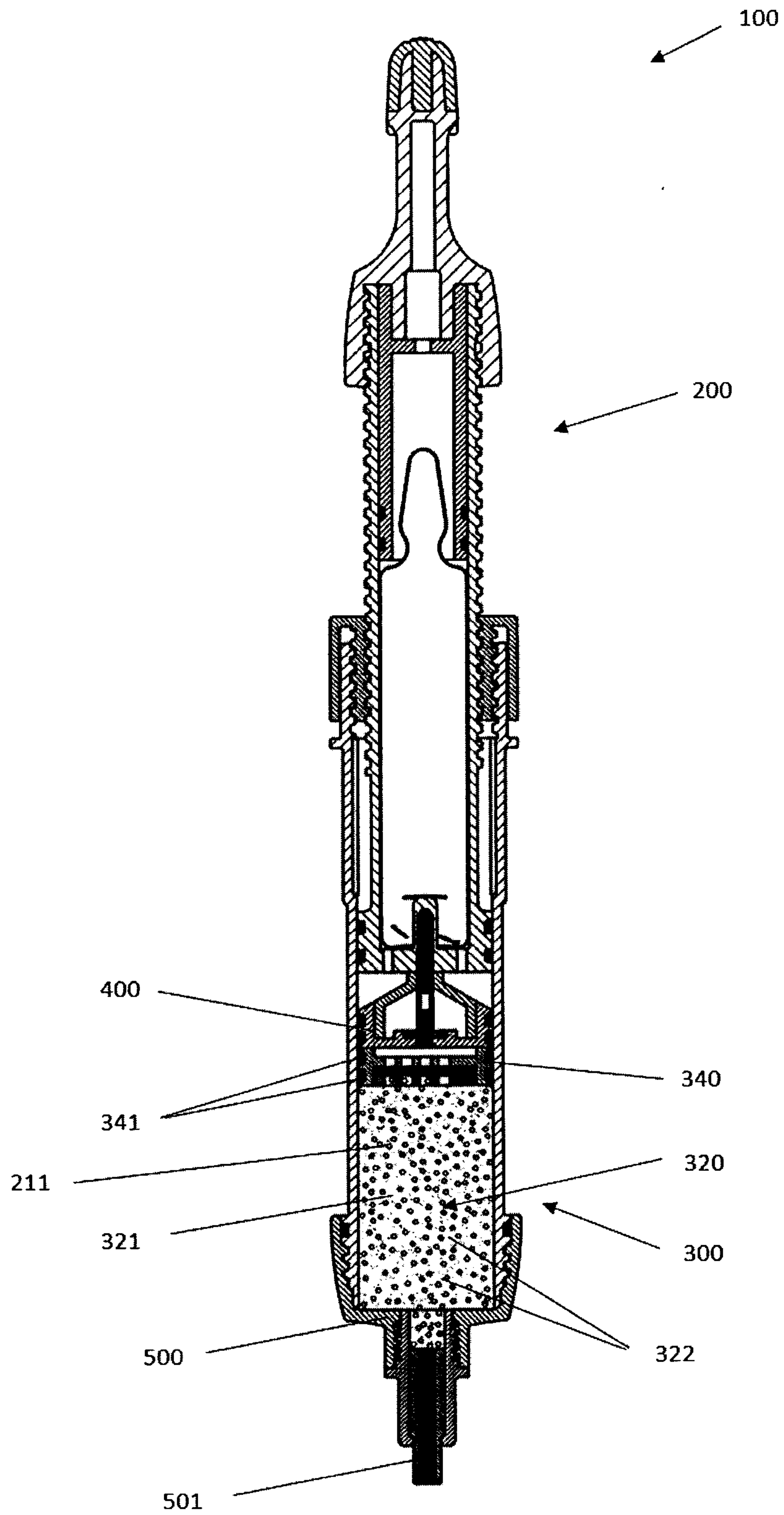


Fig. 5



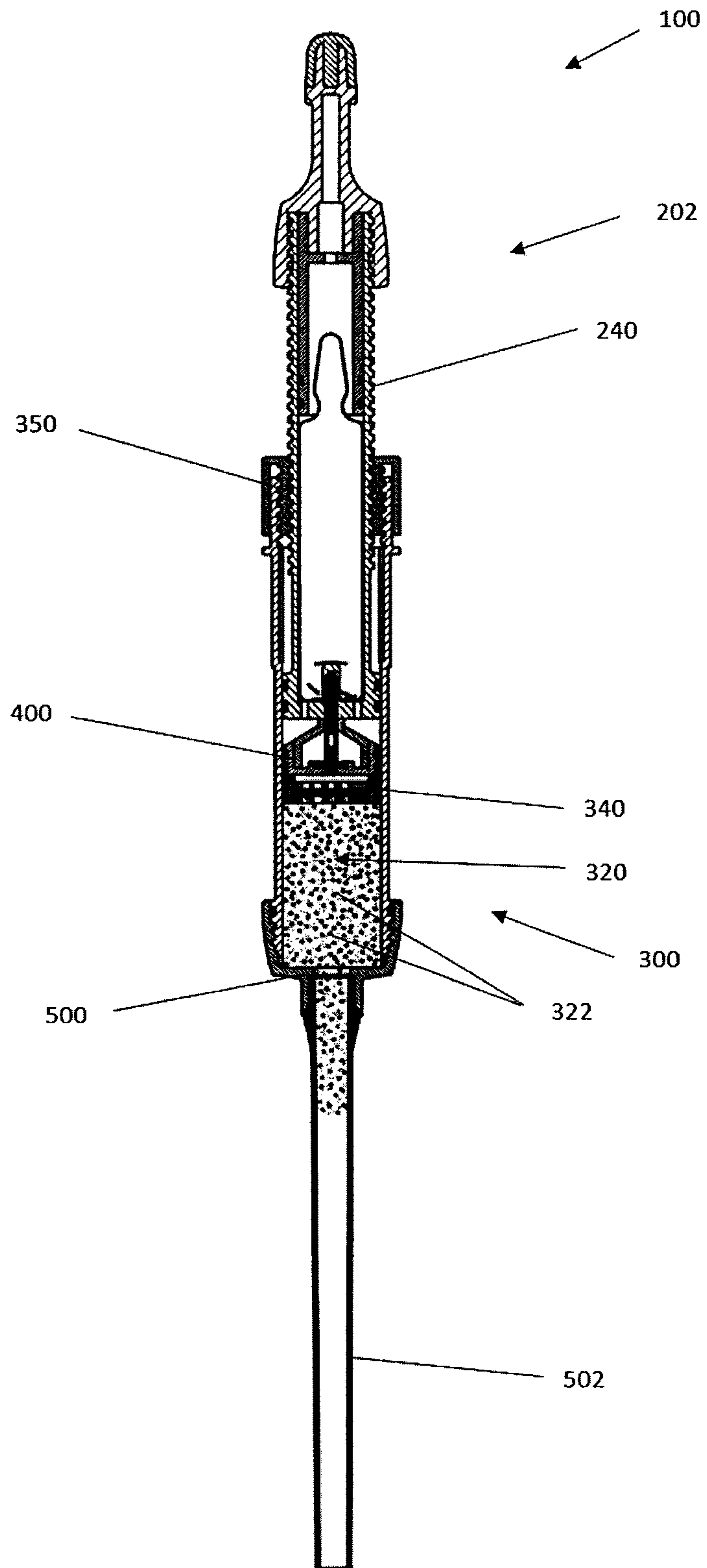


Fig. 6

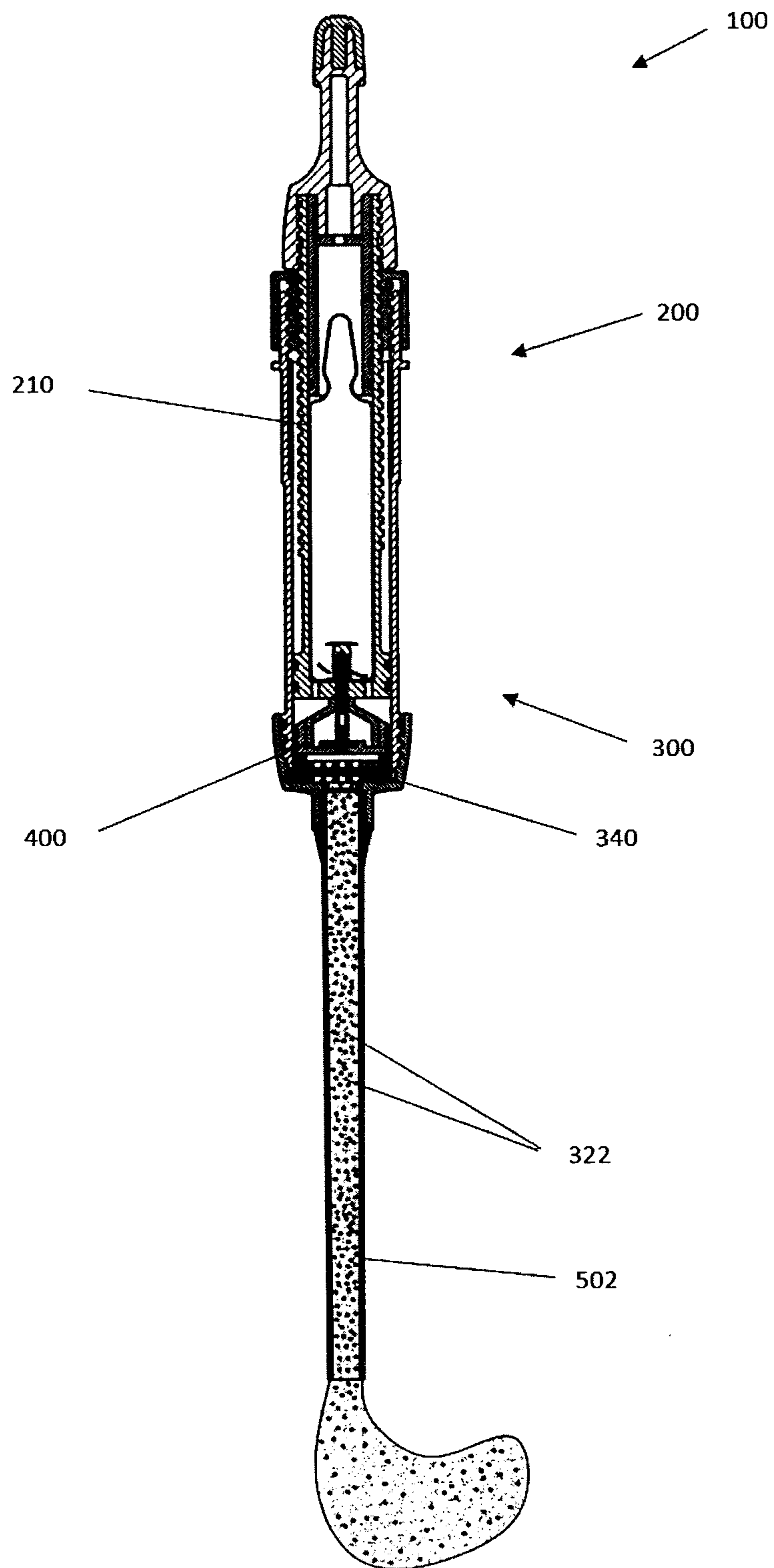


Fig. 7

600

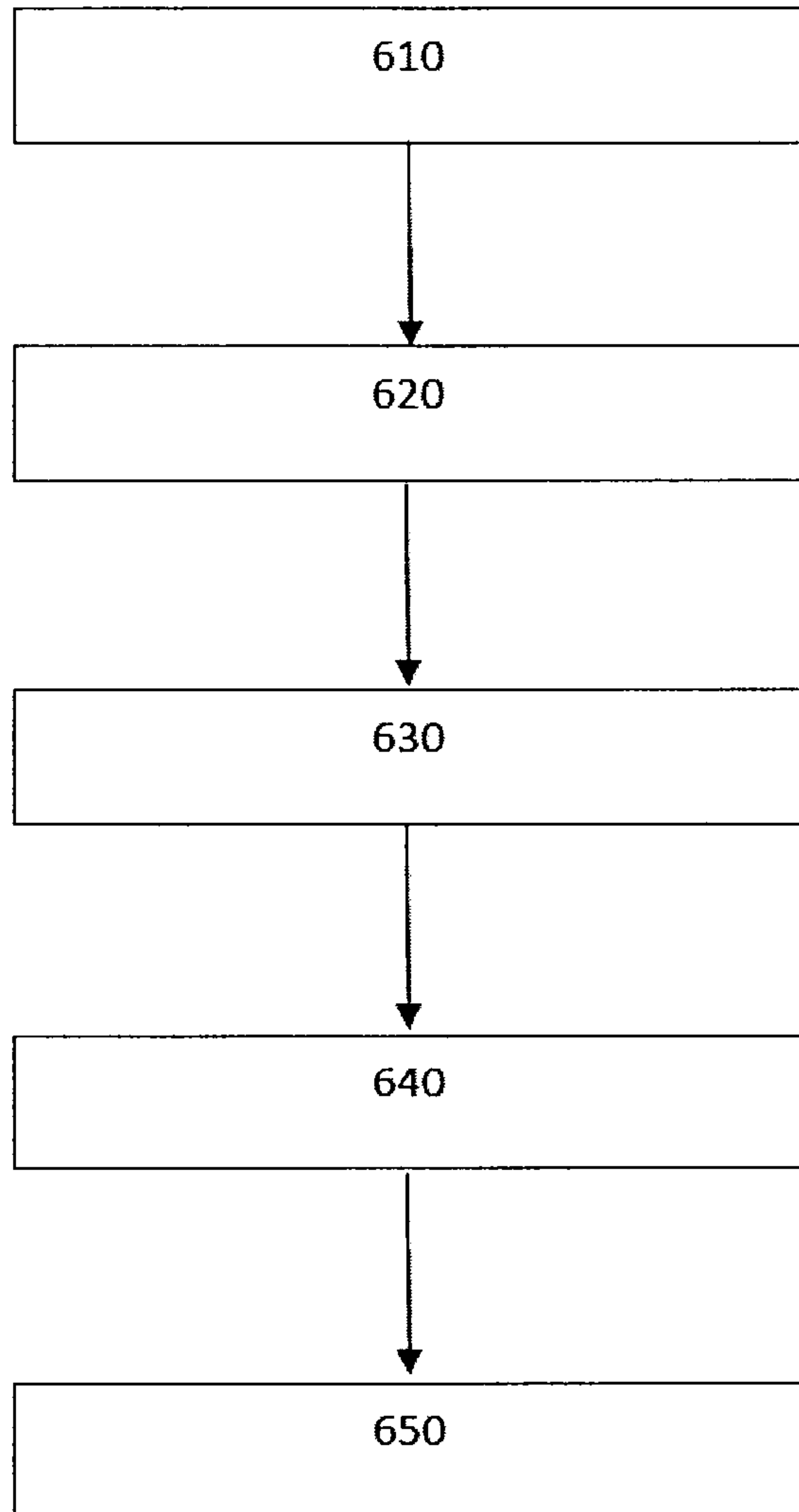


Fig. 8