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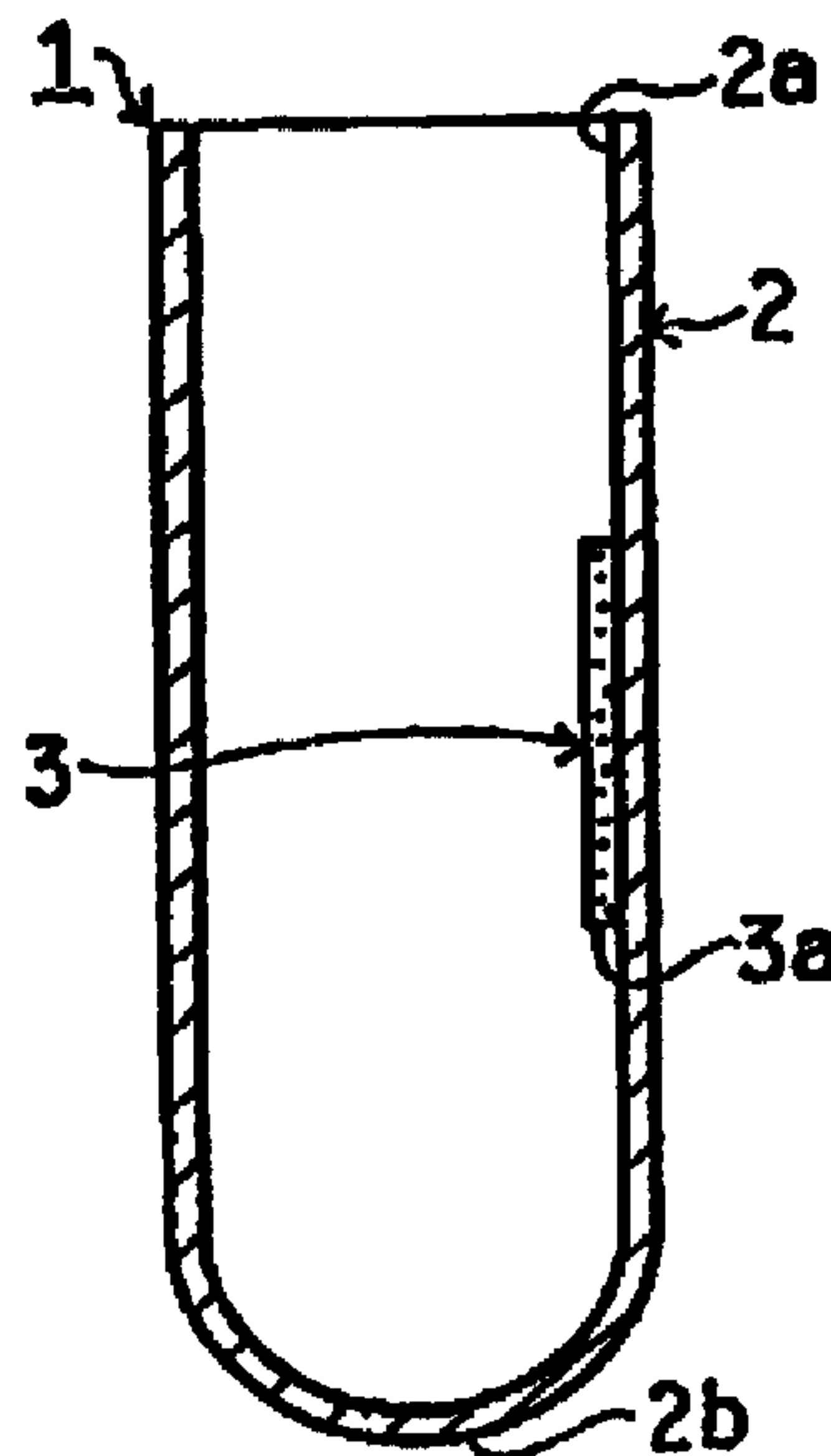
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(54) **RESERVOIR ET PROCEDE POUR TEST SANGUIN**

(54) **BLOOD TEST CONTAINER AND BLOOD TEST METHOD**



(57) Réservoir et procédé pour test sanguin permettant de prélever du sang et d'en mesurer différents constituants sans difficultés et sans que la personne effectuant le test soit en contact avec le sang. Un réservoir (1) de test sanguin auquel est fixé un réactif (3) de test sanguin est placé à l'intérieur d'un réservoir (2) à fond tubulaire, ou bien ce réservoir (1) comprend également un deuxième cylindre à fond tubulaire dont le diamètre est plus petit que celui du premier réservoir tubulaire, le réactif (3) étant fixé à au moins une de la surface intérieure du réservoir tubulaire ou de la surface extérieure du deuxième réservoir tubulaire. Ce procédé consiste à introduire le sang dans tout réservoir (1) et mettre le sang ou ses constituants en contact avec le réactif (3).

(57) A blood test container and a blood test method for making it possible to easily collect the blood and to easily measure various components in the blood without allowing a tester to come into contact with the blood. A blood test container (1) having a blood test reagent (3) fixed thereto is disposed inside a tubular bottomed container (2), or such a blood test container further comprising a second tubular bottomed cylinder having a diameter smaller than that of the first tubular container, and the blood test reagent (3) is fixed to at least one of the inner surface of the tubular container or the outer surface of the second tubular container. The blood test method comprising introducing the blood into any one of the blood test containers (1) and bringing the blood or the blood components into contact with the blood test reagent (3).



## A B S T R A C T

A blood test container and a blood test method are provided which facilitate the procedures starting from blood  
5 collection and ending with measurement of various components present in the blood while eliminating a risk for a tester to come into contact with the blood.

A blood test container 1 having a closed-bottom tubular  
container 2, a closed-bottom second tubular container having  
10 a diameter smaller than that of the tubular container 2 for accommodation therein, and a blood test reagent 3 secured onto at least one of an inner face of the tubular container and an outer face of the second tubular container. A blood  
test method comprising, in sequence, introducing blood into  
15 any one of the aforementioned blood test containers 1 and allowing the blood or its component to contact the blood test reagent 3.

## S P E C I F I C A T I O N

## BLOOD TEST CONTAINER AND BLOOD TEST METHOD

5     **TECHNICAL FIELD**

          The present invention relates to a blood test container for use in clinical examinations or testing of human and animals, and more particularly to a blood test container by which a whole procedure starting from blood collection and  
10    ending with measurement of blood components can be carried out with the use of a single container.

**BACKGROUND ART**

          The blood component testing as heretofore practiced in  
15    clinical examinations and the like is accomplished according to the following procedure. First, blood is collected by using an injector or a vacuum blood-collecting tube. Next, the blood either transferred into a test tube or introduced into the blood-collecting tube is centrifuged to separate  
20    int serum or plasma and solid matter. Subsequently, the serum or plasma separated is distributed into separately-prepared test containers for measurements.

          An equipment for carrying out such measurements is commercially available, for example, under the product name  
25    "ORTHO HCV·Ab QUICKPACK" from Orthoclinical Diagnostics Co.,

Ltd. With the use of this testing equipment, HCV antigen screening test can be performed, for example, after serum or plasma is dripped on a reagent of the testing equipment such as by a dropping pipet.

5           However, the aforementioned conventional test method has required a tester to remove a cover from the blood-collecting tube and distribute the blood into metering cups during the blood collection and measurement. Thus, several opportunities have existed for the tester to contact the  
10 blood. This has imposed a risk for the tester to acquire infectious HIV, hepatitis and the like.

          It is an object of the present invention to provide a blood test container and a blood test method which can facilitate the practice of a series of procedures starting  
15 from blood collection and ending with measurement of various blood components while reducing the chance for the tester to contact the blood.

#### **DISCLOSURE OF THE INVENTION**

20           The blood test container according to the present invention includes a bottom-closed tubular container and a blood test reagent fixedly accommodated in the tubular container.

          For the blood test container according to the present  
25 invention which secures the test reagent within the bottom-closed blood test container, (1) the blood or its

component (referring to serum or plasma previously separated from the blood) is introduced into the tubular container where it is allowed to contact the blood test reagent, or alternatively, (2) the blood is introduced into the tubular container and subsequently centrifuged so that the separated blood component, such as serum or plasma, is allowed to contact the blood test reagent. Therefore, a series of procedures from collection till measurement of the blood can be carried out without the occurrence for a tester to contact the blood.

The blood test reagent may be secured onto an inner face of the tubular container, either directly or indirectly with the aid of other supplemental members. Alternatively, the blood test reagent may be secured onto an outer surface of an inner tubular container, a second tubular container, a tubular member or the like, accommodated within the tubular container.

The "securement of the test reagent onto the inner face or " securement onto the outer face", as used in describing the present invention, is not limited to the configurations whereby the test reagent is literally secured onto the inner or outer face, and encompasses configurations whereby a liquid-form test reagent is located in contact with the inner or outer face and configuration whereby a powder-form test reagent is located in contact with the inner or outer

face. Illustrating typical examples of such configurations of the blood test container, the liquid- or powder-form test reagent is located between the tubular container and any one of the inner tubular container, second tubular container and  
5 tubular member accommodated within the tubular container to contact therewith.

In accordance with the invention as recited in claim 2, the blood test container according to the present invention further includes a contact control structure effective to  
10 normally prevent the contact of blood introduced in the container with the test reagent and, when centrifuged, allow a blood component to successfully contact the test reagent. In the invention as recited in claim 2, the contact control structure operates such that it initially prevents the blood  
15 introduced into the tubular container from contacting the test reagent but, when centrifuged, permits the separated blood component to contact the test reagent.

In accordance with the invention as recited in claim 3, the aforementioned contact control structure includes an  
20 inner container portion extending along an inner face toward a bottom of said tubular container and perforated at its bottom to have a hole, and a solid member accommodated in the inner container portion for closing the hole and configured to fall down through the hole when centrifuged.

25

Also, the blood test reagent is provided onto an inner face of the tubular container and/or an outer face of the inner container portion. Due to the presence of the solid member which closes the bottom hole of the inner container portion, 5 the blood, when introduced into the tubular container, is initially retained to stay within the tubular container. As centrifuging is subsequently applied, the solid member is caused to fall down and the blood starts to build up in the bottom of the tubular container. After centrifugation, the 10 separated serum or plasma is brought into contact with the test reagent.

In accordance with the invention as recited in claim 4, the contact control structure includes an open-ended tubular member accommodated in the tubular container and an annular 15 member radially extending between the outer face of the tubular member and the inner face of the tubular container to contact therewith. The annular member is positioned to initially locate below the test reagent. Also, the blood test reagent is secured onto at least one of the inner face 20 of the tubular container and the outer face of the tubular member. This construction permits the blood when introduced into the tubular member to flow through the bottom opening of the tubular member into the bottom of the tubular container. However, the annular member blocks the blood 25 which is accordingly prevented from reaching to contact with

the test reagent. When centrifuged, the blood in the tubular member is forced to move downward and then upward along the circumferential surface of the tubular member, whereby the annular member is pushed upward. Also, the blood, when centrifuged, is separated into serum or plasma and solid matter and the separated serum or plasma is brought into contact with the test reagent.

In accordance with the invention as recited in claim 5, the contact control structure includes an open-ended tubular member accommodated in the tubular container and having a bottom end brought into contact with an interior bottom face of the tubular container, and a pressing means for pressing the tubular member against the interior bottom face of the tubular container so that the blood introduced into the tubular member is prevented from leaking therefrom but, when centrifuged, a component of the blood is permitted to leak therefrom. Also, the blood test reagent is secured onto at least one of the inner face of the tubular container and the outer face of the tubular member. Since the pressing means acts to press the bottom end of the tubular member against the interior bottom face of the tubular container, the blood is initially prevented from leaking to leave the tubular member. When centrifuged, the blood is caused to leak from the tubular member while separated into serum or plasma and solid matter. As a result, the serum or plasma separated is

brought into contact with the test reagent.

In accordance with the invention as recited in claim 6, the contact control structure includes an open-ended tubular member secured onto the inner face of the tubular container, and a solid member secured adjacent a bottom end of the tubular member for closing a bottom opening of the tubular member and adapted to fall through the bottom opening when centrifuged. Also, the test reagent is secured within the tubular member to locate at a position above the solid member. In an initial condition where the test reagent is placed within the tubular member and the bottom opening of the tubular member is closed by the solid member, the blood when introduced into the tubular container is prevented from contacting the test reagent. The subsequent centrifugation causes the solid member to fall down while separating the blood into serum or plasma and solid matter. The falling of the solid member permits the separated serum or plasma to move into the tubular member and contact the test reagent.

In accordance with the invention as recited in claim 7, for the blood test container according to the invention as recited in claim 4, the inner and outer peripheral surfaces of the annular member are brought into abutment against the outer face of the tubular member and the inner face of the tubular container, respectively, with the aid of paraffin of the formula  $C_nH_{2n+2}$  (where n is 18 - 22, preferably 22 - 24).

In an initial condition, the contact of blood with the test reagent is blocked by the intervention of the annular member. The blood, when collected and then centrifuged, is separated into serum or plasma and solid matter. The  
5 paraffin, when subsequently heated to a temperature of not below its melting point, is caused to melt. This permits the annular member to freely move vertically. As a result, the serum or plasma is allowed to push the annular member upward and reach to contact the test reagent. That is, the  
10 application of heat after centrifugation results in bringing the serum or plasma into contact with the test reagent.

For the blood test container according to the invention as recited in claim 8, the contact control structure includes an open-ended tubular member having a smaller  
15 diameter than the tubular container and accommodated in the tubular container. The blood test reagent is secured onto at least one of the inner face of the tubular container and the outer face of the tubular member. Also, a space between the tubular container and the tubular member, inclusive of a  
20 region where the blood test reagent is secured, is sealed by a sealing member comprised of thixotropic material having a viscosity of 5,000 - 500,000 centipoise at 25 °C. Due to the presence of the sealing member which seals the space, the blood when introduced into the tubular member is  
25 prevented from flowing straight into the space. Following

centrifugation causes the thixotropic sealing member to shift in location toward a bottom of the tubular container, thereby unsealing the space. When the blood test container is subsequently turned upside down or slanted, the separated  
5 serum or plasma is allowed to enter the space where it contacts the blood test reagent for reaction therewith.

For the blood test container according to the invention as recited in claim 9, the aforementioned contact control structure includes a flexible inner resin tube accommodated  
10 in the tubular container and having an outer peripheral surface portion brought into circumferential contact with an inner face of the tubular container. One end portion of the inner tube is dimensioned to have an outer diameter smaller than an inner diameter of the tubular container so that its  
15 outer peripheral surface is separated from the inner face of the tubular container to define a space therebetween. The blood test container further includes a communicating member disposed within the space so as to be moveable. Also, the blood test reagent is located within the space and secured  
20 onto the inner face of the tubular container or onto the outer face of the inner tube.

In accordance with the invention as recited in claim 9, the blood is introduced into the inner tube. In the case where the inner tube is opened at its bottom, the blood when  
25 introduced is brought straight into a bottom of the tubular

container. In the alternative case where the inner tube is closed at its bottom, the blood is retained within the inner tube.

5 In either case, the blood is initially prevented from reaching to contact the test reagent, due to the presence of the circumferential contact of the inner tube peripheral portion and the tubular container inner face that keeps the blood away from the space within which the test reagent is located. When the blood test container is subsequently  
10 centrifuged, the communicating member is forced to move toward the circumferential contact region and finally release the circumferential contact of the outer peripheral surface portion of the inner tube and the inner face of the tubular container. As a result, the separated serum or  
15 plasma is allowed to enter the space where it contacts the blood test reagent for reaction therewith.

For the blood test container according to the invention as recited in claim 9, the inner tube may specifically be opened at its top and bottom ends and an outer diameter of  
20 its top end may be made smaller than an inner diameter of the tubular container, as recited in claim 10. In this case, the blood when introduced into the inner tube is allowed to pass through the bottom opening of the inner tube down into a bottom of the tubular container. The inner tube  
25 has an upper peripheral surface portion terminating in its

top end, which is spaced from the inner face of the tubular container to provide a space therebetween. The test reagent is secured within this space. The inner tube also has a lower peripheral surface portion terminating in its bottom end, which is brought into circumferential contact with the inner face of the tubular container. Accordingly, the blood when introduced into the inner tube is initially prevented from contacting the test reagent. When centrifuged, the communicating member is caused to move downward and act to release the circumferential contact of the lower peripheral surface portion of the inner tube and the inner face of the tubular container. As a result, the centrifugally-separated serum or plasma is brought into contact with the blood test reagent.

For the blood test container according to the invention as recited in claim 9, the inner tube may be closed at its bottom and an outer diameter of a near bottom portion of the inner tube may be made smaller than an inner diameter of the tubular container to space a lower peripheral surface portion of the inner tube from the inner face of the tubular container, as recited in claim 11. The remaining portion, i.e., the upper peripheral surface portion of the inner tube is held in circumferential contact with the inner face of the tubular container. Accordingly, the blood is prevented from reaching to contact the test reagent. After collection

of the blood, the blood test container is turned upside down and subsequently centrifuged. The centrifugation serves to separate serum or plasma from the blood. Concurrently, the communicating member is caused to move toward the upper  
5 portion of the tubular container, i.e., downwardly within the reversed blood test container. The communicating member while moved acts to release the circumferential contact of the upper peripheral surface portion of the inner tube with the inner face of the tubular container. The separated  
10 serum or plasma is then allowed to enter the space defined between the lower peripheral surface portion of the inner tube and the inner face of the tubular container and contact the blood test reagent.

The blood test container according to the invention as  
15 recited in claim 12 further includes a bottom-closed second tubular container having a diameter smaller than that of the tubular container for its accommodation within the tubular container. The blood test reagent is secured onto at least one of the inner face of the tubular container and the outer  
20 face of the second tubular container. The test reagent in the form of a liquid or powder may be placed between the tubular container and the second tubular container, as stated earlier. After introduction of the blood into the second tubular container, a stopper may be placed on the

blood test container to close its top opening, for example. When the blood test container is subsequently turned upside down or slanted, the blood is caused to leave the second tubular container and enter the space between the tubular container and the second tubular container. Within the space, the blood contacts and reacts with the blood test reagent secured onto the inner face of the tubular container and/or the outer face of the second tubular container. The reaction results can be observed visually or measured by using a measuring equipment such as a spectrophotometer.

In the blood test container according to the invention as recited in claim 13, the second tubular container is provided at its bottom with a plurality of through-holes having diameters of 0.1 - 10  $\mu\text{m}$ . Also, the blood test reagent is secured onto at least one of the inner face of the tubular container and the outer face of the second tubular container. The blood, when introduced into the second tubular container, is initially retained within the second tubular container. When needed, the blood test container is subsequently centrifuged. Then, the serum or plasma present in the blood is forced to pass through the hole and starts to build up in the bottom of the tubular container. After centrifugation, the serum or plasma can thus be brought into contact with the test reagent.

In accordance with the invention as recited in claim

14, the second tubular container is provided at its bottom with a plurality of through-holes having diameters of 10 - 400  $\mu\text{m}$ , and a porous bottom region including the plurality of through-holes is located at a position below the test  
5 reagent. Also, the blood test reagent is secured onto at least one of the inner face of the tubular container and the outer face of the second tubular container. The blood, when introduced into the second tubular container, is allowed to gradually leak through the through-holes into the tubular  
10 container. Accordingly, the blood introduced into the second tubular container is restricted from flowing rapidly into the outer tubular container. The gradual build-up of the blood in the tubular container retards the contact thereof with the test reagent. When needed, the blood test  
15 container is subsequently centrifuged. Then, the blood, while separated into serum or plasma and solid matter, is transferred from the second tubular container into the outer tubular container. As a result, the serum or plasma can be brought into contact with the test reagent.

20 For the blood test container according to the invention as recited in claim 15, the space between the tubular container and the second tubular container, inclusive of a region where the blood test reagent is secured, is sealed by a sealing member comprised of water-soluble material. When  
25 the blood is collected in or distributed into the blood test

container, the blood is thus restricted from immediately flowing into the space between the inner face of the tubular container and the outer face of the second tubular member.

When in use, the blood is introduced into the second tubular

5 container. After optional centrifugation, the blood test container is turned upside down or slanted, so that a blood sample such as serum or plasma is brought into contact with the aforementioned water-soluble material. In a while after their contact, the water-soluble material is caused to  
10 dissolve. The blood sample is then allowed to enter the space between the tubular container and the second tubular container and contact the blood test reagent for reaction therewith.

For the blood test container according to the invention  
15 as recited in claim 16, the space between the tubular container and the second tubular container, inclusive of a region where the blood test reagent is secured, is sealed by a sealing member fabricated from material having a melting point of not below 40 °C. The blood when introduced into  
20 the blood test container is thus prevented from accidentally flowing straight into the space defined between the tubular container and the second tubular container. After the blood sample is introduced into the second tubular container, the blood test container is centrifuged when needed. The blood  
25 test container is then turned upside down or slanted. The

sealing member, when subsequently heated to a temperature of above its melting point, is caused to melt. The blood sample is then allowed to enter the space where it contacts the blood test reagent and a reaction thereof is initiated.

5       The blood test container according to the invention as recited in claim 17 further includes a stopper. The stopper has a first stopper portion terminating in its bottom end and having a relatively small diameter dimensioned to be press fitted into a top opening of the second tubular  
10 container, and a second stopper portion upwardly neighboring the first stopper portion and configured to be press fitted into a top opening of the tubular container. The first stopper portion is provided on its peripheral surface with a groove extending upwardly from its bottom end to points  
15 which are located above its peripheral surface region that is to be press fitted in the second tubular portion. The second tubular container is provided on its inner face with a groove extending downwardly from its top end to points which are located below its inner face region that receives  
20 the first stopper portion.

When in use, the blood is introduced into the second tubular container, with the stopper being either held attached to or detached from the blood test container. When detached, the stopper is reattached to the blood test  
25 container after the blood introduction. In this instance,

attachment of the stopper is accomplished in such a way to stagger the groove on the first stopper portion from the groove on the second tubular container. This prevents the blood from entering the aforementioned space. When in measurement, the blood test container is centrifuged, when needed. Subsequently, the stopper is rotated to a position where the groove on the first stopper portion comes into alignment with the groove provided on the inner face of the second tubular container, thereby assuring the provision of a flow path communicated with the space between the second tubular container and the tubular container. When the blood test container is then turned upside down or slanted, the blood is caused to pass through the flow path into the space where it is contacted with the blood test reagent.

For the blood test container according to the invention as recited in claim 18, a top opening of the second tubular container is sealed by a polymer or metal film having a thickness up to 100  $\mu\text{m}$ . When in measurement, the polymer or metal film is partially broken to provide an open region through which a tubular member is inserted for introduction of the blood into the second tubular container. The blood while distributed is thus prevented from entering the space between the second tubular container and the tubular container. Next, the blood test container is centrifuged, when needed, and then turned upside down. This allows the

blood sample to enter the space between the second tubular container and the tubular container and react with the blood test reagent.

For the blood test container according to the invention  
5 as recited in claim 19, the top opening of the second tubular container is sealed by a film formed of material having a melting point of not below 40 °C. This film is partly broken to provide an open region through which a tubular member or the like is inserted for introduction of  
10 the blood sample into the second tubular container. This accordingly prevents the blood sample from flowing straight into the space between the second tubular container and the tubular container. Subsequently, the blood test container is centrifuged when needed, turned upside down or slanted,  
15 and then heated to a temperature of not below 40 °C. This results in melting the film formed of material having a melting point of not below 40 °C. The blood sample is then brought immediately into the space between the tubular container and the second tubular container, where it  
20 contacts the blood test reagent for reaction therewith.

In accordance with the invention as recited in claim 20, the blood test container as recited in any one of claims 12 - 19 includes a serum or plasma separating medium accommodated in the second tubular container. Accordingly,  
25 the centrifugation steadily separates the serum or plasma

from the blood and bring the separated serum or plasma into contact with the blood test reagent for reaction therewith.

The blood test container according to the invention as recited in claim 21 further includes a bottom-closed second tubular container which has a diameter smaller than that of the tubular container and is accommodated in the tubular container. The second tubular container is provided at its bottom with a downwardly-projecting trap portion for trapping erythrocyte and adjacent the trap portion with a hemocyte separating portion with a plurality of through-holes having diameters of 0.1 - 20  $\mu\text{m}$ .

When in use, a blood sample is introduced into the second tubular container. The subsequent centrifugation causes serum or plasma to pass through the through-holes to outside the trap portion. However, the hemocyte, because of its high specific gravity, is retained to stay within the trap portion. As a result, only the serum or plasma is allowed to leave the trap portion to enter the space between the second tubular container and the tubular container and contact the blood test reagent. It should be understood here that the centrifuging operation is not always required. In an exemplary case where the blood is vacuum collected by reducing the interior pressure of the blood test container, this pressure reduction creates a suction force which acts to pass the blood sample through the trap portion to thereby

filter the serum or plasma.

In the blood test container according to the invention as recited in claim 22, the second tubular container is provided at its bottom with a plurality of through-holes. A  
5 layer consisting of 0.1 - 200  $\mu$ m hydrophilic fine particles is further placed to overlies the through-holes. When in use, the blood is first introduced into the second tubular container. When subsequently centrifuged, for example, the serum or plasma is induced to pass through the layer  
10 consisting of 0.1 - 200  $\mu$ m hydrophilic fine particles and through the through-holes into the space between the second tubular container and the tubular container. On the other hand, the hemocyte is retained within the second tubular container to stay over the hydrophilic fine particle layer.  
15 As a result, the serum or plasma alone can be brought into contact with the blood test reagent secured onto the inner face of the tubular container and/or the outer face of the second tubular container. The above centrifuging operation is not essential. For example, when the blood is vacuum  
20 collected by reducing the interior pressure of the blood test container, the pressure reduction creates a suction force which acts to pass the blood sample through the hydrophilic fine particle layer to thereby filter the serum or plasma.

25 In accordance with the invention as recited in claim

23, the second tubular container of the blood test container according to the invention as recited in claim 22 comprises a tubular member opened at it both ends and a bottom member secured onto the bottom end of the tubular member and having  
5 a plurality of through-holes. That is, the plurality of through-holes can be provided in the bottom of the second tubular container of the blood test container according to the invention as recited in claim 22 by perforating the closed bottom of the tubular container, or alternatively, by  
10 securing a perforated bottom member onto the open bottom of the tubular member.

In accordance with the invention as recited in claim 24, the second tubular container of the blood test container according to the invention as recited in claim 12 has a hole  
15 at its bottom. This hole is closed by a water-soluble cover secured onto the bottom of the second tubular container.

For the blood test container according to the invention as recited in claim 24, when the blood is introduced into the second tubular container, it is initially prevented from  
20 contacting the blood test reagent, due to the presence of the water-soluble cover which closes the bottom hole of the second tubular container. However, the water-soluble cover has a tendency to dissolve into the water content either in the blood or in the serum or plasma separated when the blood  
25 is centrifuged. Accordingly, either with the lapse of time

or after centrifugation, the water-soluble cover material is caused to dissolve, whereby the blood, serum or plasma is permitted to flow into the space between the second tubular container and the outer tubular container and contact the blood test reagent for reaction therewith.

In accordance with the invention as recited in claim 25, the second tubular container of the blood test container according to the invention as recited in claim 12 also has a hole at its bottom. A metal or magnet cover is placed within the second tubular container in such a fashion as to close the aforementioned hole. Accordingly, when the blood is introduced into the second tubular container, its contact with the blood test reagent is prevented, because of the intervention of the water-soluble cover which closes the bottom hole of the second tubular container.

When in measurement, the cover member, if formed of a metal, is magnetically moved from outside by using an external magnet and, if formed of a magnet, by using an external metal or magnet, so that the bottom hole of the second tubular container is caused to expose. As a result, the blood introduced into the second tubular container or the serum or plasma separated from the introduced blood by the following centrifugation is allowed to pass through the bottom hole of the second tubular container and enter the space between the second tubular container and the outer

tubular container. This results in bringing the blood, serum or plasma into contact with the blood test reagent for reaction therewith.

In accordance with the invention as recited in claim 5 26, the blood test reagent accommodated in the blood test container according to the invention as recited in claim 24 or 25 is partly exposed. The remaining portion of the test reagent is covered with a coating layer so that its contact with the blood is prevented. This configuration serves to 10 suppress undesired swelling of the blood test reagent and thus eases ascertainment of test results.

In accordance with the invention as recited in claim 27, for the blood test container according to the invention as recited in claim 1, a sliding switch is mounted, for 15 vertical movement, to a side wall of the tubular container in such a manner as to grip the side wall. The blood test reagent is secured to a sliding switch portion located within the tubular container.

Accordingly, after introduction of the blood into the 20 tubular container, the blood test reagent can be brought into contact with the introduced blood for reaction therewith by operating the sliding switch to move the blood test reagent downwardly.

That is, the contact of the blood with the blood test 25 reagent can be initially prevented by selecting a volume of

the blood introduced such that its level is located in elevation below a bottom edge of the blood test reagent. Also, when in measurement, the blood test reagent can be immersed in the blood, serum or plasma for contact therewith simply by operating the sliding switch.

In accordance with the invention as recited in claim 28, the blood test container according to the invention as recited in claim 27 further includes a tube having a smaller diameter than the tubular container and accommodated in the tubular container. The tube has a bottom end located at a position below the lowest position that the sliding switch can assume. When in measurement, the blood is introduced into the tube. Since the bottom end of the tube is located at a position below the lowest position that the sliding switch can assume, the blood introduced is hardly allowed to adhere to the sliding switch mounted on the side wall of the tubular container. Accordingly, in an exemplary case where the tubular container is provided with an elongated cutout or the like for vertical movement of the sliding switch therealong, the blood is prevented from leaking through the cutout to outside.

Preferably, the aforementioned tube is located axially centrally of the tubular container. While not intended to limit the invention, the following techniques (1) - (3) can be utilized to locate the tube at such a position. (1) A

lid member is provided closing a top opening of the tubular container and the top end of the tube is secured onto a bottom face of the lid member as by an adhesive. (2) A stopper is fitted into the top opening of the tubular container and the top end of the tube is secured onto a bottom face of the stopper. The securement can be achieved with the aid of an adhesive or by threading the top end of the tube into the stopper. (3) Engaging means is provided for engageably suspending the the top end of the tube from the open end of the tubular container.

A blood test container according to the invention as recited in claim 29 further includes a closed-bottom second tubular container arranged to accommodate the tubular container mounting the sliding switch, as well as a stopper provided to simultaneously close respective top openings of those two tubular containers. Also, those two tubular containers are both reduced in interior pressure. The second tubular container may be detached either after the blood is collected according to a vacuum blood-collecting technique or, when needed, after the serum or plasma is centrifugally separated from the blood. The measurement can be accomplished in the same manner as used for the blood test container as recited in claim 27 or 28. A series of procedures from blood collection till measurement of various blood components can thus be readily practiced while

eliminating the chance for the tester to contact the blood.

In accordance with the invention as recited in claim 30, the blood test container according to the invention as recited in any one of claims 2 - 28 is reduced in interior  
5 pressure. This allows the blood to be readily introduced into the blood test container according to a vacuum blood-collecting technique.

In accordance with the blood test method as recited in claim 31, the blood test can be readily accomplished by  
10 introducing the blood into the blood test container as recited in any one of claims 2 - 30 and allowing the blood or its component to contact the aforementioned blood test reagent.

In accordance with the blood test method as recited in  
15 claim 32, the blood test can be readily accomplished by introducing the blood into the blood test container as recited in any one of claims 2 - 31, centrifuging the blood and then allowing a component of the blood to contact the blood test reagent. The blood component, as used herein,  
20 may be serum or plasma, for example. The blood test container as recited in claim 33, includes a closed-bottom tubular container and a test reagent for immunochromatography fixed within said tubular container. In accordance with the blood test container as recited in  
25 claim 34, a portion of said test reagent for

immunochemistry is exposed and the remaining portion thereof is covered with a protective layer so that the contact of the test reagent for immunochemistry with blood or the like is prevented at the remaining portion.

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**BRIEF DESCRIPTION OF THE DRAWINGS**

Figure 1 is a transverse sectional view, showing one embodiment of the blood test container in accordance with the present invention.

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Figure 2 is a transverse sectional view, showing one exemplary construction of the blood test container, in accordance with the present invention, wherein an interior pressured of the tubular container is reduced.

5        Figures 3(a) and 3(b) are transverse sectional views which explain blood test procedures when the blood test container shown in Figure 1 is used, respectively.

10       Figures 4(a) and 4(b) are transverse sectional views which explain blood test procedures when the blood test container shown in Figure 2 is used, respectively.

Figure 5 is a transverse sectional view, showing one embodiment of the blood test container in accordance with the invention as recited in claim 3.

15       Figure 6 is a transverse sectional view, showing one exemplary construction of the blood test container, in accordance with the invention as recited in claim 3, wherein an interior pressured of the tubular container is reduced.

20       Figure 7 is a transverse sectional view which explains the blood test container in accordance with the invention as recited in claim 10.

25       Figure 8 is a transverse sectional view, showing one exemplary construction of the blood test container, in accordance with the invention as recited in claim 10, wherein an interior pressured of the tubular container is reduced.

Figures 9(a) and 9(b) are transverse sectional views which explain blood test procedures when the blood test container shown in Figure 7 is used, respectively.

Figures 10(a) and 10(b) are transverse sectional views  
5 which explain blood test procedures when the blood test container shown in Figure 8 is used, respectively.

Figure 11 is a transverse sectional view, showing one embodiment of the blood test container in accordance with the invention as recited in claim 4.

10 Figure 12 is a transverse sectional view, showing one exemplary construction of the blood test container, in accordance with the invention as recited in claim 4, wherein an interior pressure of the tubular container is reduced.

Figures 13(a) and 13(b) are transverse sectional views  
15 which explain blood test procedures when the blood test container shown in Figure 11 is used, respectively.

Figures 14(a) and 14(b) are transverse sectional views which explain blood test procedures when the blood test container shown in Figure 12 is used, respectively.

20 Figure 15 is a transverse sectional view, showing one embodiment of the blood test container in accordance with the invention as recited in claim 14.

Figure 16 is a transverse sectional view, showing one exemplary construction of the blood test container, in  
25 accordance with the invention as recited in claim 14,

wherein an interior pressure of the tubular container is reduced.

Figures 17(a) and 17(b) are transverse sectional views which explain blood test procedures when the blood test container shown in Figure 15 is used, respectively.

Figures 18(a) and 18(b) are transverse sectional views which explain blood test procedures when the blood test container shown in Figure 16 is used, respectively.

Figure 19 is a transverse sectional view, showing one embodiment of the blood test container in accordance with the invention as recited in claim 5.

Figure 20 is a transverse sectional view, showing one exemplary construction of the blood test container, in accordance with the invention as recited in claim 5, wherein an interior pressure of the tubular container is reduced.

Figures 21(a) and 21(b) are transverse sectional views which explain blood test procedures when the blood test container shown in Figure 19 is used, respectively.

Figures 22(a) and 22(b) are transverse sectional views which explain blood test procedures when the blood test container shown in Figure 20 is used, respectively.

Figure 23 is a transverse sectional view, showing one embodiment of the blood test container in accordance with the invention as recited in claim 6.

Figure 24 is a transverse sectional view, showing one

exemplary construction of the blood test container, in accordance with the invention as recited in claim 6, wherein an interior pressure of the tubular container is reduced.

Figure 25 is a transverse sectional view which explains  
5 a modified embodiment of the blood test container in accordance with the invention as recited in claim 3.

Figure 26 is a transverse sectional view of the blood test container in accordance with the invention as recited in claim 7.

10 Figure 27 is a transverse sectional view, showing the condition when the blood test container shown in Figure 26, after blood collection, was centrifuged.

Figure 28 is a transverse sectional view, showing the condition when the blood test container shown in Figure 26,  
15 after the centrifugation, was heated.

Figure 29 is a transverse sectional view, showing the blood test container in accordance with the invention as recited in claim 12.

Figure 30 is a transverse sectional view which explains  
20 the blood test container in accordance with the invention as recited in claim 15.

Figure 31 is a transverse sectional view which explains the blood test container in accordance with the invention as recited in claim 17.

25 Figure 32 is an exploded perspective view of the blood

test container shown in Figure 31.

Figures 33(a) and 33(b) are a perspective view of the second tubular container for use in the blood test container shown in Figure 31 and a sectional view taken along the line  
5 A-A of Figure 33(a), respectively.

Figure 34 is a perspective view of the stopper for use in the blood test container shown in Figure 31.

Figure 35 is a transverse sectional view which explains the blood test container in accordance with the invention as  
10 recited in claim 18.

Figure 36 is a transverse sectional view, showing the blood test container in accordance with the invention as recited in claim 12 wherein the serum or plasma separating medium is accommodated in the second tubular container.

15 Figures 37(a) and 37(b) are transverse sectional views which explain the blood test container in accordance with the invention as recited in claim 21, respectively.

Figure 38 is a transverse sectional view which explains the blood test container in accordance with the invention as  
20 recited in claim 22.

Figure 39 is a transverse sectional view which explains a modified embodiment of the blood test container shown in Figure 38.

Figure 40 is a transverse sectional view, showing the  
25 blood test container of Example 30.

Figure 41 is a transverse sectional view, showing the blood test container of Example 31.

Figure 42 is a transverse sectional view which explains the blood test container in accordance with the invention as  
5 recited in claim 27.

Figure 43 is a side view of the blood test container shown in Figure 42 to which the sliding switch is mounted, when viewed from outside of the tubular container.

Figure 44 is a side view of the blood test container  
10 shown in Figure 42 to which the sliding switch is mounted, when viewed from inside of the tubular container.

Figure 45 is an enlarged sectional view taken along the line IV-IV of Figure 44.

Figure 46 is a transverse sectional view, showing an  
15 exemplary construction of the blood test container in accordance with the invention as recited in claim 28.

Figure 47 is a transverse sectional view, showing an exemplary construction of the blood test container in accordance with the invention as recited in claim 29.

20 Figure 48 is a side view which explains an alternative embodiment of the stopper for use in the blood test container shown in Figure 47.

Figure 49 shows the blood test container illustrated in Figure 42 while it is in use, Figure 49(a) is its sectional  
25 view when the blood is introduced thereinto and Figure 49(b)

is its sectional view when the blood, after centrifugation, is measured.

Figure 50 shows the blood test container illustrated in Figure 46 while it is in use, Figure 49(a) is its sectional view when the blood is introduced thereinto and Figure 49(b) is its sectional view when the blood, after centrifugation, is measured.

Figure 51 is a transverse view showing the blood test container of Example 33, Figure 51(a) is its sectional view when the blood is introduced thereinto and Figure 51(b) is its trasverse sectional view when the blood, after centrifugation, is measured.

Figure 52 is a transverse view showing the blood test container of Example 32, Figure 52(a) is its transverse sectional view when the blood is introduced thereinto and Figure 52(b) is its trasverse sectional view when the blood, after centrifugation, is measured.

Figure 53 is a transverse sectional view which explains an exemplary construction of the blood test container in accordance with the invention as recited in claim 12.

Figure 54 is a transverse sectional view, showing an exemplary construction of the blood test container in accordance with the invention as recited in claim 25 or 26.

Figure 55 is a transverse sectional view, showing an exemplary construction of the blood test container in

accordance with the invention as recited in claim 26.

Figures 56(a) and 56(b) are transverse sectional views showing an exemplary construction of the blood test container in accordance with the invention as recited in claim 10, respectively, Figure 56(a) is a sectional view showing its initial condition and Figure 56(b) is a transverse sectional view showing its condition after it was vigorously centrifuged.

Figures 57(a) and 57(b) are transverse sectional views showing an exemplary construction of the blood test container in accordance with the invention as recited in claim 10, respectively, Figure 57(a) is a sectional view showing its condition where the serum and solid matter were separated from each other and Figure 57(b) is a transverse sectional view showing its condition after it was vigorously centrifuged.

Figures 58(a) and 58(b) are transverse sectional views which explain measuring steps, with the use of the blood test container in accordance with the invention as recited in claim 10, respectively, Figure 58(a) is a transverse sectional view which explains the shifting in location of the communicating member when the container is vigorously centrifuged and Figure 58(b) is a transverse sectional view showing its condition after it was vigorously centrifuged.

Figures 59(a) and 59(b) are transverse sectional views

which explain the blood test container in accordance with the invention as recited in claim 11, respectively, Figure 59(a) is a sectional view showing its initial condition and Figure 59(b) is a transverse sectional view showing its condition where the blood was introduced thereinto.

Figures 60(a) and 60(b) are transverse sectional views, showing the condition where the serum and solid matter in the blood test container shown in Figure 59 were separated from each other and the condition where the container was turned upside down, respectively.

Figures 61(a) and 61(b) are transverse sectional views which explain measuring steps, with the use of the blood test container in accordance with the invention as recited in claim 11, respectively, Figure 61(a) is a transverse sectional view which explains the shifting in location of the communicating member by centrifugation and Figure 61(b) is a transverse sectional view showing its condition after centrifuged.

## **BEST MODES FOR CARRYING OUT THE INVENTION**

Exemplary constructions of the blood test container of the present invention will be now described with reference to the drawings.

Figure 1 is a sectional view, showing a blood test container in accordance with the present invention. A blood

test container 1 has a closed-end tubular container 2, and a blood test reagent 3 secured onto an inner surface of the tubular container 2. The tubular container 2 may be made from suitable materials, such as a synthetic resin and glass, preferably from transparent materials which permit visual inspection of an interior of the tubular container 2. Although illustrated in Figure 1 as having a circular cross section, the tubular container 2 may be configured to have a polygonal cross section such as a triangle or rectangle, or alternatively, another arbitrary-shaped cross section.

The test reagent 3 may be of any suitable type for use in the measurement of components present in serum or plasma. The test reagent 3 is preferably in the form of solid for its easy securement onto the inner surface of the tubular container 2. However, any viscoelastic test reagent which can be secured somehow onto the inner surface of the tubular container 2 may also be used. As stated above, the test reagent 3 may be in the form of a liquid or powder, or in the form of being coated on or adsorbed by an insoluble carrier. The type of the test reagent 3 is not particularly limited, so long as its contact with blood components allows the detection or quantitative determination thereof by visual, colorimetric, fluorometric or reflection spectral analysis.

Examples of the test reagents 3 include 1) those, like immunochromatography for detection of hepatitis B antigens, which are used, for component determination, in the form of being included in a film-, disc- or stick-form medium, such as a test paper, cloth, nitrocellulose membrane or glass fiber (test paper or the like may be at its surface covered with a film); 2) liquid-form reagents such as liquid-form pH indicators or liquid-form reagents for measurement of biochemistry- or immunity-associated items; 3) immunological reagents such as TIA and the like utilizing freeze-dried antibodies, enzymes or proteins, or powder-form reagents utilizing chemical substances and the like; 4) reagents such as antibodies, proteins, chemical substances or the like in the form of being coated on a wall surface; 5) liquid- or powder-form reagents in the form of being adsorbed by latex particles or colloidal particles of metals. More specifically, the class 1) is illustrated by reagents for detection of HBs antigen (product name: Quick Chaser HBsAg, manufactured by Mizuho Meddy Co., Ltd., product name: Dyna Screen HBsAg, manufacture by Dynabbot Co., Ltd.). The class 2) is illustrated by a phenolphthalein solution and BTB solution.

Illustrative of the class 3) are TIA reagents utilizing freeze-dried antibodies such as CRP, RF and the like.

Illustrative of the class 4) are chromoreagents or

enzymes fixed onto needle-like glass fibers, and antigens or antibodies directly coated on a container inner surface.

Illustrative of the class 5) are liquid-form reagents in the form of antigens or antibodies held by synthesized polymer latex particles or colloidal metals, and dry-form reagents made by freezing those liquid-form reagents.

The technique used to secure the aforementioned test reagent 3 onto the inner surface of tubular container 3 is not particularly specified, including the use of pressure-sensitive adhesive tapes or adhesives.

The size of tubular container 2 is not particularly specified. The tubular container 2 may be of any suitable size, so long as it can collect blood and be subjected to centrifugation and permits the reaction of the test reagent 3 accommodated therein with the serum or plasma separated from the collected blood.

Figure 2 is a sectional view, illustrating another exemplary construction of the blood test container in accordance with the present invention. The blood test container 4 differs in construction from the blood test container 1 shown in Figure 1 in that the former includes a stopper 5 for closing a top opening 2a of the tubular container 2. The material used to constitute the stopper 5 is not particularly specified, and can be natural or synthetic rubber, such as silicone rubber, which exhibits

rubber elasticity.

For the blood test container 4, the tubular container 2 is closed by the stopper 3 and its interior is reduced in pressure. The degree of pressure reduction is selected such  
5 that the blood can be introduced promptly into the interior of tubular container 2 when a blood-collecting needle is at one end inserted into a patient's blood vessel and at another end inserted through the stopper 5. Generally, the interior of the tubular container 2 is reduced approximately to 0.1 -  
10 0.8 atmospheric pressure.

For blood test containers 1 and 4 shown in Figure 1 and Figure 2, the test reagent 3 is secured onto the inner wall of tubular container 2 so that it locates a certain distance above a bottom 2b of the tubular container 2. It is thus  
15 preferred that collection of blood 6 is carried out so as for its top surface A to stay below a bottom edge 3a of the test reagent 3, as shown in Figure 3(a) and Figure 4(a), whereby the contact of blood 6 with the test reagent 3 is prevented. Also, as shown in Figure 3(b) and Figure 4(b),  
20 once centrifuged to separate the blood into serum or plasma 6a and solid matter 6b, the subsequent inclination of the tubular container 2 allows a ready contact of the test reagent 3 with the serum or plasma 6a.

That is, for the blood test containers 1, 4, the  
25 securement of the test reagent 3 at the intermediate height

of the tubular container 2 leads to the provision of a contact control structure according to the present invention.

The centrifugal operation may be performed at 500 - 5,000 r.p.m for the approximate period of 5 minutes - 30 minutes.

In the shown exemplary constructions which follow, the tubular container 2 and test reagent 3 can be made from the same materials as those described above. The stopper 5 can also be configured analogously to the stopper 5 used for the blood test container 4.

Figure 5 is a transverse sectional view of a blood test container in accordance with the invention as recited in claim 3. For the blood test container 7, an inner container portion 8 is accommodated in the tubular container 2. The inner container portion 8 is made from the same or different material from the tubular container 2, and is secured at its upper end to an inner surface of the tubular container 2. The inner container portion 8 is configured such that its diameter is gradually reduced in dimension toward the bottom 2b of the tubular container 2 as it extends downwardly from its upper end.

The inner container portion 8 has at its bottom end a hole 8a which is closed by a solid member 9. The solid member 9 is initially secured to the inner container portion 8, as by adhesives when needed, so that it is prevented from

falling downwardly and the hole 8a is kept closed as shown.

The solid member 9 is designed to fall downwardly through the hole 8a by a centrifugal force produced when the centrifuging follows the blood introduction into the inner container portion 8. The solid member 9 may be placed in position, either without or with the aid of adhesives. In the latter case, the adhesive force must be adjusted to the level that permits the solid member to fall when the centrifugal force is applied thereto. The outer diameter and material type of the solid member 9, as well as the diameter of the hole 8a, are also selected to permit the solid member 9 to fall upon centrifugation.

The solid member 9 can be made from any suitable material which allows the above-described action of the solid member 9. Useful materials include, for example, synthetic resin beads such as polystyrene beads, and polymer compounds and rubbers which have thixotropic properties, such as an oxidized ellagic acid. For the purpose of facilitating the fall of the solid member 9, the thixotropic polymer compounds or rubbers, among those materials, are preferably used to constitute the solid member 9.

In the blood test container 7, the test reagent 3 is secured onto the inner wall surface of the tubular container 2 so that it is positioned above the aforementioned solid member 9.

In the blood testing procedure using the blood test container 7, blood is introduced into the inner container portion 8 and the blood test container 7 is subsequently centrifuged. The centrifuging condition is not particularly specified. Centrifuging may be carried out at 500 r.p.m. - 5,000 r.p.m. for the period of 5 - 30 minutes, analogously to the case for the blood test container 1.

During the centrifugation, the blood is held staying in the bottom portion 2b of the tubular container 2 while it is separated into serum or plasma and solid matter. This permits the test reagent 3 disposed outwardly of the inner container portion 8 to readily contact the serum or plasma. Preferably, the stopper 5 is fitted into the opening 2a of the tubular container 2, as shown in Figure 6, and the interior pressure of the tubular container 2 is reduced. The reduction in interior pressure of the tubular container 2 allows the prompt introduction of blood into the inner container portion 8 disposed within the tubular container 8.

Figure 25 is a transverse sectional view, showing a modified embodiment of a blood test container in accordance with the invention as recited in claim 3. In this modified embodiment, the inner container portion 8, in the form of a tube having a diameter smaller than that of the tubular container 2, is placed within the tubular container 2. That is, the inner container portion 8 is not limited to the

tapered configuration shown in Figure 5 wherein tapering is made to gradually reduce its diameter toward the bottom portion 2b, and may be in the tubular form as shown in Figure 25. Although not depicted in Figure 25, the inner  
5 container portion 8 is fixedly connected to the tubular container 2 by a rib which is not shown.

In the modified embodiment shown in Figure 25, the inner container portion 8 is at its bottom opened to define a hole 8a which is closed by the rubber-made solid member 9.  
10 The solid member 9 can be made from the aforementioned materials other than rubber, whereby the blood is initially prevented from leaking from the inner container portion 8 toward outside and contacting the test reagent, as analogous to the construction embodiment shown in Figure 5. The  
15 following centrifugation causes the solid member 9 to fall downwardly and the blood in the tubular container 2 to separate into serum or plasma and solid matter. This assures the subsequent contact of the serum or plasma with the test reagent 3.

20 In Figures 5, 6 and 25, the test reagent 3 may be secured onto an outer surface of the inner container portion 8, or onto both the outer surface of the inner container portion 8 and the inner surface of the tubular container 2. The test reagent may be placed, in the form of a liquid or  
25 powder, between the tubular container 2 and the inner

container portion 8. The inner container portion 8 may be integrally connected to the separately-formed tubular container 2, or alternatively, integrally formed with the tubular container 2.

5           Figure 7 is a transverse sectional view of a blood test container in accordance with the invention as recited in claim 13. The blood test container 10 includes the test reagents 3, 3 respectively secured onto an inner wall surface of the tubular container 2. On the inner wall  
10 surface of the tubular container 2, the test reagents 3, 3 are positioned in pairs to face toward each other. However, this is not intended to exclude the case where the reagent 3 is singularly secured onto one location on the inner wall surface.

15           The tubular container 2 accomodates therein a second tubular container 11 which has a reduced diameter relative to the tubular container 2. The second tubular container 11 provides a space into which blood is introduced. The second tubular container 11 can be made from various suitable  
20 materials including, for example, synthetic resins such as polyeethylene terephthalate and glass. The material type is not particularly specified. Although desired to be made transparent, the second tubular container 11 needs not be made transparent since the measurement results can be  
25 obtained outside the second tubular container 11.

The second tubular container 11 is fixedly connected to the tubular container 2 as by a rib which is not shown. In the case where the below-described stopper 5 is used, the second tubular container 11 may be secured to the stopper 5, as shown in Figure 8.

A bottom opening of the second tubular container 11 is closed by a perforated plate 12 secured thereto. The perforated plate 12 has a number of through-holes 12a having diameters of 0.1 - 10  $\mu\text{m}$ . The perforated plate 12 can be made from suitable synthetic resins, such as polyethylene terephthalate, or glass.

The perforated plate 12 may be adhesively secured to the second tubular container 11. The perforated plate 12 may be integrally formed with the second tubular container 11. The perforated plate 12 is not necessarily positioned to locate its bottom end contiguous with the bottom edge of the second tubular container 11, and may be positioned to locate slightly above the bottom edge.

When the blood is introduced into the second tubular container 11, the through-holes having diameters of 0.1 - 10  $\mu\text{m}$  restrict the blood from passing therethrough and leaving the second tubular container 11. The blood is initially introduced into the second tubular container 11, as shown in Figure 9(a). The subsequent centrifugation forces the serum or plasma 6a to pass through the perforated plate 12, while

the solids 6b in the blood, such as hemocyte and clot, are held remaining in the tubular container 11, as shown in Figure 9(b). In the situation as shown in Figure 9(b), the test reagent 3 can be brought into contact with the serum or  
5 plasma 6a for measurement.

Also for the blood test container 10, the stopper 5 is preferably disposed to close a top opening 2a of the tubular container 2, as shown in Figure 8, and an interior of the tubular container 2 is reduced in pressure. In this case,  
10 the pressure differential can be utilized to draw the blood into the second tubular container 11 so that the blood 6 is collected in the blood test container 10, as shown in Figure 10(a). The subsequent centrifugation forces the serum or plasma 6a to pass through the second tubular container 11,  
15 while the solid matter 6b such as clot is held remaining in the tubular container 11, as shown in Figure 10(b). This permits the test reagent 3 to be brought into contact with the serum or plasma 6a for measurement.

The test reagent 3 may be secured onto an outer surface  
20 of the second tubular container 11, or onto both the second tubular container 11 and the tubular container 2. The test reagent may be placed, in the form of a liquid or powder, between the tubular container 2 and the second tubular container 11. The inner container portion may be integrally  
25 connected to the separately-formed tubular container, or

alternatively, integrally formed with the tubular container.

Figure 11 is a transverse sectional view of a blood test container in accordance with the invention as recited in claim 4. For the blood test container 13, a tubular  
5 member 14 having a diameter smaller than the tubular container 2 is accomodated within the tubular container 2. The tubular member 14 is opened at its both ends and is secured to the tubular container 2 as by a rib which is not shown. This tubular member 14 can be constructed from the  
10 materials used in forming the tubular container 2, and its material type is not particularly specified.

An annular member 15 is placed near the bottom edge of the tubular member 14 to come into circumferential contacts with the outer surface of the tubular member 14 and with the  
15 inner surface of the tubular container 2. The annular member 15 can be made from materials of rubber elsticity, such as narural and synthetic rubber.

The annular member 15 is initially located below the test reagent 3. When blood is introduced into the tubular  
20 member 14, the blood is allowed to pass through the bottom of the tubular member 14 and reaches an interior of the tubular container 2. However, the annular member 15 restricts the blood from moving upwardly thereacross, as shown in Figure 13(a). The subsequent centrifugation forces  
25 the blood in the tubular member 14 to move downwardly, so

that the annular member 15 is pushed upwardly, as shown in Figure 13(b). Also, the centrifugation separates the blood into serum or plasma and solid matter. In this instance, the annular member 15 is caused to move upward to a position  
5 above a bottom edge of the test reagent 3, as shown in Figure 13(b). As a result, the serum or plasma is brought into contact with the test reagent 3.

For the blood test container 13, the stopper 5 may be mounted to the tubular container 2 to close its top opening  
10 2a, as shown in Figure 12. In such an instance, an interior of the tubular container 2 is reduced in pressure. The following insertion of a blood-collecting needle through the stopper 5 thus results in the prompt suction of blood into the tubular member 14.

Also for the blood test container 13, the test reagent  
15 3 may be secured onto an outer surface of the tubular member 14, or onto both the tubular member 14 and the tubular container 2. The tubular member 14 may be integrally connected to the separately-formed tubular container 2, or  
20 alternatively, integrally formed with the tubular container.

Figure 15 is a transverse sectional view showing a blood test container embodiment in accordance with the invention as recited in claim 14. For the blood test container 16, a bottom-closed second tubular container 17 is  
25 placed within the tubular container 2. The second tubular

container 17 is secured to the tubular container 2 as by a rib which is not shown. A bottom portion of the tubular container 17 is provided with a number of through-holes 17a having diameters of 10 - 400  $\mu\text{m}$ , and this porous portion having those through-holes is positioned to locate below the test reagent 3.

The material used to form the tubular container 17 is not particularly specified. It can be formed from synthetic resins such as polypropylene and polyethylene terephthalate, glass and the like.

The porous portion having through-holes 17a may be made from a separate material. That is, a porous member having through-holes with the above-specified diameters, such as a perforated plate, may be secured to the hollow tubular member near its bottom end.

In either case, when the blood 6 is introduced into the tubular container 17, the serum or plasma therein is allowed to gradually pass through the container but the solid matter is initially prevented from passing through the container, due to the size of the through-holes within the range of 10 - 400  $\mu\text{m}$ , as shown in Figure 17(a).

The centrifuging, subsequent to the introduction of the blood into the second tubular container 17, forces the blood to flow into the tubular container 2 where the blood is separated into the serum or plasma 6a and solid matter 6b

(See Figure 17(b)).

Then, it becomes possible to conduct measurements by contacting the serum or plasma 6a with the test reagent 3. Also for the blood test container 16, the stopper 5 may  
5 preferably be used to close the opening 2a of the tubular container 2 with an interior of the tubular container 2 being reduced in pressure, as shown in Figure 16. In this case, the blood can be readily introduced into the second tubular container 17 by reducing the interior pressure of  
10 the second tubular container 17, either with or without reducing the interior pressure of the tubular container 2.

The test reagent 3 may be secured onto an outer surface of the second tubular container 11, or onto both the second tubular container 11 and the tubular container 2. The test  
15 reagent may be placed, in the form of a liquid or powder, between the tubular container 2 and the second tubular container 11. The inner container portion may be integrally connected to the separately-formed tubular container, or alternatively, integrally formed with the tubular container.

20 Figure 19 is a transverse sectional view of a blood test container embodiment in accordance with the invention as recited in claim 5. For the blood test container 18, a tubular member 19 having a diameter smaller than that of the tubular container 2 is accommodated in the tubular container  
25 2. The tubular member 19 is opened at its both ends, and

its bottom end extends onto an inner bottom surface of the tubular container 2 for contact therewith. The tubular member 19 can be made from suitable glass or synthetic resins such as polypropylene and polyethylene terephthalate. However, the use of synthetic resins is preferred for their increased ability to initially prevent the blood from leaking from the tubular member 19 to enter the tubular container 2.

A cap 20 is provided as a means for pressing the bottom end of the tubular member 19 against a bottom of the tubular container 2. The cap 20 can be made from various suitable materials such as synthetic resins and glass. The cap 20 must be configured such that, when it is attached to the tubular container 2, its bottom surface 20a presses the tubular member 19 downwardly sufficiently to restrict the blood, if introduced into the tubular member 19, from leaking to the tubular container 2 side. To attain such an action, a material type of the cap 20 and a length of the tubular member 19 must be determined according to the particular dimension of the tubular container 2 used.

For the blood test container 18, blood is introduced into the tubular member 19, followed by the attachment of the cap 20, as shown in Figure 21(a). Alternatively, one end of a blood-collecting needle may be thrust into the cap 20 so that the blood can be introduced into the tubular

member 19 directly from the blood-collecting needle. In an initial state, the blood is held residing in the tubular member 19 and its leakage toward the tubular container 2 side is prevented, because the bottom end of the tubular member 19 is being pressed against the bottom wall of the tubular container 2.

When the blood test container 18 is centrifuged, the blood acts to push open a space between the bottom end of the tubular member 19 and the bottom face of the tubular container 2, and escapes from the space to outside of the tubular member 19, as shown in Figure 21(b), while it is separated into the serum or plasma 6a and solid matter 6b. The serum or plasma 6a is accordingly brought into contact with the test reagent 3 for measurements.

For the blood test container 18, the stopper 5, instead of the cap 20 serving as a pressing means, may be attached to close the opening 2a of the tubular container 2, as shown in Figure 20. In such a case, the configuration of the stopper 5 must be carefully selected to allow the stopper to press the tubular member 19 downwardly and acts in the same fashion as the cap 20 for the blood test container 8.

Where the stopper 5 is fitted in the tubular container 2, the blood can be drawn and introduced quickly into the tubular member 19 by reducing the internal pressures of the tubular container 2 and tubular member 19.

For the blood test container 18, the test reagent 3 may be secured onto an outer surface of the tubular member 19, or onto both the tubular member 19 and the tubular container 2. The test reagent may be placed, in the form of a liquid or powder, between the tubular member 19 and the tubular container 2. The inner container portion may be integrally connected to the separately-formed tubular container, or alternatively, integrally formed with the tubular container.

Figure 23 is a transverse sectional view, illustrating a blood test container according to the invention as recited in claim 6. For the blood test container 22, a tubular member 23 having a diameter smaller than that of the tubular container 2 is secured onto an inner wall surface of the tubular container 2. The tubular member 23 is opened at its both ends and can be formed of suitable materials including synthetic resins such as polypropylene and polyethylene terephthalate, glass and the like. The tubular member 23 can be secured to the inner face of the tubular container 2 by the use of adhesives, pressure-sensitive adhesive tapes and the like.

The test reagent 3 is secured within the tubular member 23. Accordingly, the test reagent 3 is secured not directly but indirectly to an inner wall of the tubular container 2. A solid member 24 is inserted in the tubular member 23 for placement at the bottom opening thereof. The solid member

24 is secured, as by adhesives when needed, such that it can be held in position when no force is applied thereto, but is caused to drop when centrifuged.

5 The solid member 24 can be formed of the same material as used for the solid member 9 shown in Figure 5.

10 When in use, blood is initially introduced into the tubular container 2 of the blood test container 22 in such a way that the entry of the blood into the tubular member 23 can be avoided. Also, the amount of the blood introduced is regulated so that a blood surface level does not reach a top end of the tubular member 23. This assures no entry of the blood into the tubular member 23, since the tubular member 23 is closed at its bottom opening by the solid member 24. The subsequent centrifuging of the blood test container 22 causes the solid member 24 to drop, as well as causing the blood to separate into serum or plasma and solid matter.

15 Now that the solid member 24 has fallen from inside of the tubular member 25, the subsequent inclination of the blood test container 22 allows the serum or plasma to contact the test reagent 3. However, in the case where the blood has been initially brought in level to an intermediate height of the tubular member 23, i.e., to the elevation of the test reagent 3, the serum or plasma is allowed to spontaneously flow into the tubular member 23 to contact the test reagent 3. This permits the measurement without the

need to incline the blood test container 22.

Also for the blood test container 22, the stopper 5 may be used to close the opening 2a of the tubular container 2, as shown in Figure 24, and its interior may be reduced in  
5 pressure. Such reduction in interior pressure of the tubular container 2 suction draws the blood into the tubular container 2, facilitating the blood collection thereinto. In Figure 24, a pair of the tubular members 23 is disposed to face toward each other. The inner container portion may  
10 be integrally connected to the separately-formed tubular container, or alternatively, integrally formed with the tubular container.

Figure 26 is a transverse sectional view, illustrating a blood test container in accordance with the invention as  
15 recited in claim 7. The blood test container 31 is constructed in the same configuration as the blood test container 13 shown in Figure 11, according to the present invention as recited in claim 4, with the exception that the annular member 15 is mounted in a different fashion.  
20 Accordingly, the description of the like parts is omitted by referring to the description given above in explaining the embodiment shown in Figure 11.

For the blood test container 31, the annular member 15 is fixedly placed between the outer surface of tubular  
25 member 14 and the inner surface of tubular container 2 with

the aid of paraffin 32. In this case, the compositions of the formula  $C_nH_{2n+2}$  (n is 18 - 22, preferably 22 - 24) are used for the paraffin 32. Examples of such paraffins include octadecane ( $C_{18}H_{38}$ , melting point of 28 °C),  
 5 nonadecane ( $C_{19}H_{40}$ , melting point of 32 °C), icosane ( $C_{20}H_{42}$ , melting point of 37 °C), monoicosane ( $C_{21}H_{44}$ , melting point of 42 °C), diicosane ( $C_{22}H_{46}$ , melting point of 47 °C), triicosane ( $C_{23}H_{48}$ , melting point of 52 °C), tetraicosane ( $C_{24}H_{50}$ , melting point of 57 °C), and pentaicosane ( $C_{25}H_{52}$ , melting point of 62  
 10 °C).

These paraffins are caused to melt when heated to temperatures of not below their respective melting points as indicated above. For the blood test container 31, the annular member 15 is initially secured to both the tubular  
 15 member 14 and tubular container 2 by the paraffin 32, as shown in Figure 26. When blood is introduced into the tubular member 14, the annular member 15 withstands the flow of blood so that the annular member 15 is not forced to move upwardly, as analogously to the instance for the blood test  
 20 container 13 shown in Figure 11.

The following centrifugation separates the blood into the serum or plasma 6a and the solid matter 6b, as shown in Figure 27. The aforementioned paraffin 32 is caused to melt when subsequently heated to a temperature of not below its  
 25 melting point, permitting the annular member 15 to freely

move vertically, as shown in Figure 28. This allows the serum or plasma 6a to push the annular member 15 upward and contact the test reagent 3. Also, the inner container portion may be integrally connected to the separately-formed tubular container, or alternatively, integrally formed with the tubular container.

Figure 29 is a transverse sectional view, showing a blood test container embodiment in accordance with the invention as recited in claim 12. For the blood test container 41, a closed-bottom second tubular container 42 is accommodated within the tubular container 2. The tubular container 42 can be made from suitable glass or synthetic resins such as polyethylene terephthalate.

The blood test reagent 3 is secured onto an inner surface of the tubular container 2. The stopper 5 is fittingly pressed into the opening 2a of the tubular container 2 to seal its interior.

The tubular container 2, blood test reagent 3 and stopper 5 are constructed analogously to those of the above-described test container 1 in accordance with the invention shown in Figures 1 and 2.

The second tubular container 42 having a diameter smaller than the tubular container 2 is accommodated in the tubular container 2.

When in use, the interior pressure of the tubular

container 2 is reduced, a vacuum blood-collecting needle is inserted through the stopper 5, and blood is introduced into the tubular container 42 by using a vacuum blood collection technique. An alternative sequence may be detaching the  
5 stopper 5, introducing the blood into the second tubular container 42, and again attaching the stopper 5.

The blood test container is subsequently centrifuged. Centrifuging may be achieved at 500 - 5,000 r.p.m. for about 5 minutes - 30 minutes. This results in the separation of  
10 the blood into serum or plasma and solid matter. When the blood test container 41 is subsequently turned upside down, the serum or plasma previously held in the second tubular container 42 is now permitted to flow into a space X defined between the outer surface of second tubular container 42 and  
15 the inner surface of tubular container 2 and finally contact the blood test reagent 3 to react therewith.

This permits the visual observation of the reaction result from outside of the tubular container 2, or permits measurement of the reaction result by the use of a measuring  
20 equipment such as a spectro photometer.

Preferably, the blood test container 41 is closed tight by using the stopper 5 so that the blood can be introduced promptly into the second tubular container 42 upon reduction of an interior pressure of the tubular container 2. The  
25 degree of pressure reduction is generally in the approximate

range of 0.1 - 0.8 atmospheric pressure. The inner container portion may be integrally connected to the separately-formed tubular container, or alternatively, integrally formed with the tubular container.

5       The test reagent 3 may be secured onto an outer surface of the second tubular container 42, or onto both the second tubular container 42 and the tubular container 2. The test reagent may be placed, in the form of a liquid or powder, between the tubular container 2 and the second tubular  
10       container 42.

Figure 30 is a transverse sectional view, illustrating a blood test container in accordance with the invention as recited in claim 15.

For the blood test container 43, a space X defined  
15       between the second tubular container 42 and the tubular container 2 is sealed by a sealing member 44. That is, the space X containing the test reagent 3 is sealed by the sealing member 44.

The sealing member 44 is secured to locate above the  
20       blood test reagent 3, e.g., extend laterally from near a peripheral top end of the second tubular container 42 to an inner surface of the tubular container 2, as shown in Figure 30.

The sealing member 44 is formed from water-soluble  
25       material. The water-soluble material is not particularly

specified, so long as it can isolate the blood introduced in the tubular container 42 from the test reagent 3. Examples of such water-soluble materials include, but not limited to, various natural polymers, semisynthetic materials and  
5 synthetic polymers. Examples of natural polymers include chitin, chitosan, casein, gelatin, collagen, egg albumin, starch (wafer), seaweeds, carrageenan, sodium alginate, agar, xanthane gum and pullulan. Examples of semisynthetic materials include dextrin, methyl cullulose and carboxy  
10 methyl cellulose. Examples of synthetic polymers include poyvinyl alcohol, sodium polyacrylate, polymethacrylic acid, polyacrylamide, polyethylene oxide, polyetylene glycol and the like.

Exemplary commercial products for use as the water-  
15 soluble material include SOLBLON (manufactured by Icello Chemical Co., Ltd.), KURAREAR (manufactured by Kuraray Co., Ltd.), TOSLON (manufactured by Tokyo Cellophane Co., Ltd.), HI-CELLON (Nippon Synthetic Film Co., Ltd.), VINYLON Film (manufactured by Kuraray Co., Ltd.), BOBLON (manufactured by  
20 Nippon Synthetic Film Co., Ltd.), EMBLER (manufactured by Unitica Co., Ltd.), EXCEED (manufactured by Okura Kogyo Co., Ltd.), EVAL (manufactured by Kuraray Co., Ltd.) and the like.

When in use, the blood is introduced into the second  
25 tubular container 42, followed by centrifugation. The

centrifugation can be achieved under the same conditions as employed for the blood test container 41.

The blood, when centrifuged, is separated into serum or plasma and solid matter. When the blood test container 43  
5 is subsequently turned upside down, the serum or plasma is brought into contact with the water-soluble material 44 which is then caused to dissolve. This allows the serum or plasma to flow into the space X where it contacts the test reagent 3 and the reaction thereof proceeds.

10 The reaction result can be observed visually from outside, or alternatively, measured by a measuring equipment such as a spectro photometer.

While the blood test container in accordance with the invention as recited in claim 15 uses water-soluble material  
15 for the sealing member 44, the blood test container in accordance with the invention as recited in claim 13 uses material having a melting point of not below 40 °C for the sealing member 44. The material having a melting point of not below 40 °C is not particularly specified, and may be  
20 paraffin of the formula  $C_nH_{2n+2}$  (n is 18 - 22), for example.

Where the aforementioned material having a melting point of not below 40 °C is used for the sealing member 44, the blood test container 43, after being centrifuged, may be turned upside down and heated so that the sealing member 44  
25 is elevated in temperature to 40 °C or higher. The sealing

member 44 is then caused to melt, resulting in the entry of the serum or plasma into the space X where it contacts the test reagent 3 for reaction therewith. The inner container portion may be integrally connected to the separately-formed tubular container, or alternatively, integrally formed with the tubular container.

For the blood test container 43, the water-soluble material is used to form the sealing member 44. The blood test container in accordance with the invention as recited in claim 8, however, uses thixotropic material having a viscosity of 5,000 - 500,000 centipoise to form the sealing member 44. The other parts are identical in structure to the blood test container 43.

The sealing member may be made from oxidized ellagic acid or chlorinated polybutene, for example.

In such an instance, when the blood is introduced into the second tubular container 42, the immediate entry of the blood into the space X is reliably prevented by the presence of the sealing member having a thixotropic property and a viscosity within the above-specified range. During the centrifugal operation to separate the blood into serum or plasma and solid matter, the sealing member 44 is forced to move toward a bottom of the tubular container 2. As a result, sealing of the space X is deactivated. Accordingly, when the blood test container 43, after being centrifuged,

is turned upside down, the serum or plasma is brought into the space X where it contacts the test reagent 3 for reaction therewith. The inner container portion may be integrally connected to the separately-formed tubular container, or alternatively, integrally formed with the tubular container.

Figures 31 through 34 are views which explain an exemplary construction of a blood test container according to the invention as recited in claim 17.

The blood test container 45 has the tubular container 2 and the second tubular container 42. The test reagent 3 is secured onto an outer surface of the second tubular container 42.

The blood test container 45 uses a stopper 46 which, when pressed, can be fitted in both the tubular container 2 and the second tubular container 42. The stopper 46 has a first stopper portion 46a which extends upwardly from a distal end of the stopper and has such a relatively small diameter that it, when pressed, fits in the second tubular container 42. The continuous and upward extension from the first stopper portion 46a is a second stopper portion 46b which has such a relatively large diameter that it, when pressed, fits in the tubular container 2.

The first stopper portion 46a has a groove 46c on its outer periphery, which extends in a length direction, as

shown in Figures 32 and 34.

The second tubular container 42 has on its inner surface a groove 42a which extends downwardly from the opening edge 42b along a length direction, as shown in  
5 Figures 33(a) and 33(b).

The aforementioned grooves 46c and 42a extend upwardly and downwardly, respectively, from a region where the first stopper portion 46a is press fitted in the second tubular container 42.

10 When the blood test container 45 is used, blood is introduced into the second tubular container 42. In this case, the stopper 46 may be detached from the second tubular container 42 before the blood is introduced into the second tubular container 42. Alternatively, the stopper 46 may be  
15 held attached to the second tubular container 42 and the blood is introduced into the second tubular container 42 as by using a vacuum blood-collecting needle.

Subsequently, the stopper 46 is rotated to laterally align the groove 46c thereon with the groove 42a on the  
20 second tubular container 42. As a result, the grooves 42a and 46c provide a flow path which communicates the interior of the second tubular container 42 with the space X between the outer face of the second tubular container and the inner face of the tubular container.

25 The following centrifugation separates the blood into

serum or plasma and solid matter. When the blood test container 45 is then turned upside down, the serum or plasma is caused to pass through the flow path into the space X where it contacts the test reagent 3 for reaction therewith.

5           Also in the this exemplary constructions, an interior pressure of the blood test container 45 may preferably be reduced. The subsequent insertion of a blood-collecting needle or the like through the stopper 46 results in the introduction of the blood sample into the second tubular  
10 container 42 by a suction force created by the pressure reduction. Also, the inner container portion may be integrally connected to the separately-formed tubular container, or alternatively, integrally formed with the tubular container.

15           Figure 35 is a transverse sectional view which explains a blood test container in accordance with the invention as recited in claim 18. For the blood test container 51, a second tubular container 42 having a diameter smaller than that of the tubular container 2 is accommodated within the  
20 tubular container 2. The test reagent 3 is secured onto an inner surface of the tubular container 2. Also, the stopper 5 is press fitted into the opening 2a of the tubular container 2. These follow the construction of the blood test container 41 shown in Figure 29.

25           A feature of the blood test container 51 resides in its

provision of a polymer film 52 having a thickness of up to 100  $\mu\text{m}$  which serves to seal a top opening of the second tubular container 42.

5 The aforementioned polymer film 52 is not particularly specified, and may be formed of polyethylene, polyvinyl chloride or arabic gum, for example. A metal film having a thickness of up to 100  $\mu\text{m}$ , such as of aluminum, silver or copper, can also be used in the place of the polymer film 52.

10 Where the polymer film 52 is used, it may be secured to an open edge of the tubular container 42 either by heat bonding or by using a suitable adhesive. Where the metal film is used, it may be secured to an open edge of the tubular container 42 by using a suitable adhesive.

15 For the illustrated blood test container 51, the polymer film is broken through as by a needle before a blood sample is introduced into the second tubular container 42. The small thickness of the polymer film 52 or metal, up to 100  $\mu\text{m}$ , permits a needle or the like to easily break through  
20 a part of thereof. Accordingly, in an exemplary case where a vacuum blood-collecting needle is subsequently inserted through the attached stopper 5, a catheter or a blood-discharging tip of the vacuum blood-collecting needle can be easily inserted through the broken part of the polymer film  
25 52. Alternatively, the blood-discharging tip of the vacuum

blood-collecting needle may be utilized to directly break through the polymer film 52. Since the opening of the second tubular container 42 is sealed by the polymer film 52, the blood, when introduced into the second tubular container 42, is prevented from flowing into the space X defined between the outer face of second tubular container 42 and the inner face of tubular container 2.

In the testing, a blood sample is brought into the second tubular container 42 and subsequently centrifuged so that it is separated into serum or plasma and solid matter. The blood test container 51 is then turned upside down to allow the serum or plasma to pass through the broken part of the polymer film 52 and flow into the space X where it contacts the test reagent 3.

Also in the case of using the metal film in the place of the polymer film 52, the above procedure may be followed to contact the serum or plasma with the test reagent 3.

Preferably, the blood test container 51 is sealed by the stopper 5 and its interior pressure is reduced to create a suction force which acts to draw the blood promptly into the second tubular container 42.

Figure 36 is a sectional view which explains a modified embodiment of the blood test container 41. For the modified blood test container 41A, a serum separating medium 53 is accommodated in the second tubular container 42. The serum

separating medium 53 is not particularly specified, and can be illustrated by polybutene, polystyrene, oxidized ellagic acid or the like which has a specific gravity within the range of 1.00 - 1.2. These substances can also be used as a plasma separating medium, and in such a case, the serum separating medium may be utilized as an alternative of the plasma separating medium 53.

For the blood test container 41A, the serum separating medium 53 is accommodated in the second tubular container 42. This assures that the blood, when centrifuged, separates into the serum and clot. Similarly, the use of the plasma separating medium always results in separation of the blood into the plasma and solid matter.

Also for the blood test containers 43, 45, 51 according to the other exemplary constructions as descibed earlier, the serum or plasma separating medium may be accommodated in the second tubular container 42, whereby the blood, when centrifuged, can be reliably separated into the serum or plasma and the solid matter.

For the blood test containers 41, 41A, 43 and 51, securement of the second tubular container 42 to the tubular container 2 can be achieved by the sealing member 44, if one is used. Unless the sealing member 44 is used, a bridge-like connection member such as of a synethetic resin or metal may be provided which extends between an outer wall

surface of the second tubular container 42 and an inner wall surface of the tubular container 2 for connection thereof. Alternatively, an open top end of the second tubular container 42 may be connected to the stopper 5. Also, the inner container portion may be integrally connected to the separately-formed tubular container, or alternatively, integrally formed with the tubular container.

Further, the tubular container 2 may be tapered to have a decreasing diameter toward its bottom. In such a case, the second tubular container 42, when its bottom portion is brought into abutment against an inner face of the tapered portion of the tubular container 2, can be held in position within the tubular container 2. Alternatively, the tubular container 2 may be configured to carry on its inner face at least one projection by which the second tubular container 42 can be held in a predetermined position while the space X is defined between the second tubular container 42 and the inner face of the tubular container 2.

The test reagent 3 may be secured to an inner face of the tubular container 2 and/or an outer face of the second tubular container 42. The test reagent 3 may be placed, in the form of a liquid or powder, between the tubular container 2 and the second tubular container 42.

Figures 37(a) and (b) are transverse sectional views which explain a blood test container in accordance with the

invention as recited in claim 21.

For a blood test container 61, a second tubular container 62 is accommodated within the tubular container 2. The second tubular container 62 has a smaller diameter than the tubular container 2 and is at its top end secured to the stopper 5.

The second tubular container 62 has at its bottom end a trap portion 62a which is configured to project downwardly and serves to trap erythrocytes. Provided adjacent the trap portion 62a is a hemocyte separator portion 62c which has a number of through-holes 62b having diameters of 0.1 - 20  $\mu\text{m}$ .

Any suitable material can be used for the second tubular container 62, so long as the bottom-located trap portion 62a made therefrom functions to trap erythrocytes. Examples of useful materials include polymeric materials, such as polyethylene terephthalate, vinyl chloride, polyethylene, polystyrene and polypropylene, and inorganic materials or metals such as glass, iron and aluminum.

The size of the trap portion 62a may be determined depending on the particular volume of blood collected. The trap portion 62a may generally be sized in volume to about 50 % of a total volume of the blood collected, since a standard hematocrit value for human blood is around 50 %.

A number of through-holes 62b which permit serum or plasma to pass therethrough are provided adjacent the trap

portion 62a, thereby constituting the hemocyte separator  
portion 62c. The hemocyte separator portion 62c having such  
through-holes 62b can be constructed from suitable filter  
materials, or alternatively, from particles aggregated so as  
5 to form the through-holes 62b. When the blood is collected  
in the second tubular container 62 and then centrifuged, the  
separated serum or plasma is allowed to pass through the  
through-holes 62b to leave the tubular container 62, while  
the controlled size of the through-holes within the range of  
10 0.1 - 20  $\mu\text{m}$  prevents the passage of the erythrocyte which,  
because of its high specific gravity, is retained within the  
trap portion 62a. As a result, the serum or plasma passes  
through the through-holes 62b and reaches a bottom portion  
of the tubular container 2 where it is collected and stored.

15 The serum or plasma collected in the bottom portion of  
the tubular container 2, when it amounts to a certain  
volume, is contacted with the test reagent 3 and a reaction  
thereof is initiated.

In the testing, blood is introduced into the second  
20 tubular container 62 and subsequently centrifuged. This  
results in allowing the separated serum or plasma to collect  
in the bottom portion of the tubular container 2. When the  
volume of the serum or plasma collected increases and its  
level reaches the test reagent 3, a reaction therebetween is  
25 initiated immediately.

As shown in Figure 37(b), in the case where the serum or plasma separated by centrifugation is insufficient in volume to reach the test reagent 3, the reaction of the serum or plasma 63 with the test reagent 3 can be caused to start by slanting or turning the blood test container 61 upside down.

Also in this exemplary construction, an inner pressure of the blood test container 61 may preferably be reduced to the aforesated level to create a suction force which acts to draw a blood sample promptly into the second tubular container 62.

Also, the test reagent 3 may be secured to either an outer face of the second tubular container 62 or to both of the outer face of the second tubular container 62 and the inner face of the tubular container 2. The inner container portion may be integrally connected to the separately-formed tubular container, or alternatively, integrally formed with the tubular container.

Figures 38 and 39 are sectional views which explain a blood test container in accordance with the invention as recited in claim 22.

For a blood test container 71, a second tubular container 72 having a diameter smaller than that of the tubular container 2 is accommodated in the tubular container 2. Although the second tubular container 72 is depicted in

Figure 38 as if floating within the tubular container 2, the second tubular container 72 can be fixedly placed within the tubular container 2 as by using the above-described suitable structure which connects the second tubular container 42 and the tubular container 2 while assuring the space X between the outer face of the second tubular container 72 and the inner face of the tubular container 2.

For a blood test container 71, a second tubular container 72 has a bottom provided with plural through-holes 72a. Preferably, these through-holes 72a are sized in diameter to permit passage of serum or plasma but prevent passage of hemocytes therethrough, i.e., not to exceed 10  $\mu\text{m}$ . A layer 73 is provided to overlies the bottom provided with through-holes 72a, which is comprised of hydrophilic fine particles having diameters of 0.1 - 200  $\mu\text{m}$ .

In an exemplary construction shown in Figure 38, a separate bottom member 72b having the aforementioned plural through-holes 72a is secured by adhesive (not shown) to close a bottom opening of a tubular member 72c. However, those through-holes 72a may be provided in a bottom of a closed-bottom tubular container.

The 0.1 - 200  $\mu\text{m}$  diameter hydrophilic fine particles used to form the aforementioned layer is not particularly specified in type, and may be comprised, for example, of hydrophilic group-containing, e.g., carboxyl-containing

polystyrene, vinyl chloride, silica, iron oxide or sugar.

When in use, blood is introduced into the second tubular container 72. The blood, when subsequently centrifuged, is caused to separate into serum or plasma and solid matter. In such an instance, red and white blood cells and the like are held staying in or above the hydrophilic fine particle layer 73 while the serum or plasma is allowed to flow downwardly and pass through the through-holes 72a to leave the second tubular container 72. When the serum or plasma is brought into contact with the test reagent 3, a reaction thereof is caused to take place.

In the case where the serum or plasma collected is insufficient in volume to reach the test reagent 3, the contact of the serum or plasma with the test reagent 3 can be attained by inclining or turning the blood test container 71 upside down.

Preferably, the stopper 5 is pressed to fit in the tubular container 2, as shown in Figure 39, and an interior of the blood test container 71 is brought into a pressure-reduced condition. Such reduction in internal pressure of the blood test container 71 allows prompt introduction of a sample blood into the second tubular container 72 when a vacuum blood-collecting technique is utilized, and also creates a suction force which acts to draw the blood through the hydrophilic fine particle layer 73 where it is filtered

effectively, so that the serum or plasma can be brought into a bottom portion of the tubular container 2.

That is, when the internal pressure of the blood test container 71 is reduced, the blood is filtered by the  
5 hydrophilic fine particle layer 73, while drawn therethrough by a suction force created by the pressure reduction. This enables the serum or plasma in the blood to flow into the bottom portion of the tubular container 2 without the need to be separated by centrifugation. The inner container  
10 portion may be integrally connected to the separately-formed tubular container, or alternatively, integrally formed with the tubular container.

Figure 42 is a sectional view, showing an exemplary construction of a blood test container in accordance with  
15 the invention as recited in claim 27. For a blood test container 81, a sliding switch 83 is provided in such a manner as to grip a side wall 2d of the closed-bottom tubular container 2, so that it is vertically moveable along the side wall 2d. The test reagent 3 is located inside the  
20 tubular container 2 where it is attached to the sliding switch 83.

The respective constructions of the sliding switch 83 and test reagent 3 are not particularly specified, so long as they meet the requirements that the sliding switch 83  
25 should be provided in such a manner as to grip a side wall

2d of the closed-bottom tubular container 2 so that it is vertically moveable along the side wall 2d, and that the reagent 3 should be located inside the tubular container 2 where it is attached to the sliding switch 83.

5 Exemplary constructions of the sliding switch 83 and test reagent 4 will be now described with reference to Figures 43, 44 and 45. Figure 43 and Figure 44 show the configuration by which the sliding switch 83 is mounted to the tubular container 2, when viewed from outside and inside  
10 of the tubular container 2, respectively. Figure 45 is an enlarged view of a section taken along the line IV - IV of Figure 44.

As shown in Figure 43, an elongated parallel-side slot 2f is provided at a side wall 2d of the tubular container 2,  
15 which extends downwardly from its peripheral top edge 2e. The slot 2f has opposing side walls 2g, 2h that extend between an outer wing 83a and an inner wing 83b of the sliding switch 83, respectively. The outer and inner wings 83a, 83b of the sliding switch 83 are constructed in a thin-  
20 walled rectangular configuration, and both curved to conform to a curvature of the side wall 2d. The outer and inner wings 83a, 83b are joined to each other by a joining member 83c having a diameter smaller in dimension than a width of the slot 2f, so that they are brought into tight contact  
25 with the side walls 2g, 2h. This construction allows the

sliding switch to slidably move up and down along the side walls 2g, 2h when its outer wing 83a is pushed up and down by a finger force. As also shown in Figure 43, the outer wing 83a is irregularly surfaced to facilitate a finger operation by which the outer wing is pushed moved up and down. The joining member 83c of the sliding switch 83 suspends the test reagent 3 so as to locate it in an interior of the tubular container 2. Securement of the test reagent 3 to the joining member 83c can be accomplished by an arbitrary technique which uses, for example, a mechanical linkage, pressure-sensitive tape or adhesive. In this particular embodiment, the pressure-adhesive tape is used.

The sliding switch 83 can be made from suitable material such as sythetic resins.

The size of the tubular container 2 is not particularly specified. Any suitable size of the tubular container 2 can be chosen if the downward movement of the sliding switch 83, subsequenet to blood collection and optional centrifuging, permits a part of the test reagent 3 to contact the blood, serum or plasma, leading to a reaction of the test reagent 4 with components present in the blood, serum or plasma.

Figure 46 is a sectional view, showing an exemplary construction of a blood test container 90 in accordance with the invention as recited in claim 28. A tube 91 is further added to the blood test container 1 shown in Figure 42 so as

to locate axially centrally of the tubular container 2. The tube extends from the vicinity of the top opening toward a bottom of the tubular container 2 so that its bottom end 91 is located at a position below the lowest position that the sliding switch 83 can assume.

In Figure 46, the aforementioned tube 91 is shown as being at its top end 91b adhesively secured to a bottom portion of a stopper 92 that closes a top opening of the tubular container 2. However, other techniques such as described above can also be used to fixedly locate the tube at the above-stated position.

Figure 47 is a sectional view, showing an exemplary construction of a blood test container 100 in accordance with the invention as recited in claim 29. A closed-bottom tubular container 101 for housing both a whole body of the tubular container 2 and the sliding switch 83, as well as a stopper 102 for closing the respective top openings of the aforementioned two tubular containers 2 and 101, are added either to the blood test container 81 shown in Figure 42 or the blood test container 90 shown in Figure 43 (although Figure 47 illustrates a case where the blood test container 90 shown in Figure 46 is used, the stopper 92 used for the blood test container 90 is replaced by the stopper 102). Also, both of the aforementioned two tubular containers 2 and 101 are internally reduced in pressure.

The stopper 102 has a larger diameter upper portion 102a and a smaller diameter lower portion 102b. An outer face of the lower portion 102b is sized to be fittingly received by an inner face of a top opening portion of the tubular container 2. The larger diameter upper portion 102a has at its bottom portion a groove 102c into which a top opening edge 101a of the outer tubular container 101 can be inserted in an air-tight fashion.

The aforementioned tube 91 is at its top end portion 91b joined to a bottom portion of the lower portion 102b of the stopper 102. Joining can be achieved by a technique which utilizes, for example, a pressure-sensitive tape, adhesive or mechanical engagement.

In the assembly of the aforementioned blood test container 100, the reduction in internal pressure of the above-described two tubular containers 2 and 101 can be performed according to the following procedure. The stopper 102 (to which the tube 91 has been previously joined) is fittingly inserted into the top opening of the tubular container 2 carrying the sliding switch 83. This blood test container, together with the outer tubular container 101, are placed within a chamber provided with a pressure-reducing equipment, such as a vacuum pump, and then reduced in pressure to a desired level. Thereafter, the peripheral edge 101a of the top opening of the outer tubular portion

101 is fittingly inserted into the groove 102c provided in the upper portion 102a of the stopper 102. This procedure enables the pressure reduction of an interior of the tubular container 2. Otherwise, the reduction in internal pressure  
5 of the tubular container 2 will fail even if the stopper 102 is fitted therein, because the slot 2f for attachment of the sliding switch 83 defines an air passage that prevents the interior of the tubular container 2 from being brought into an air-tight condition.

10 For the stopper 102, the provision of the groove 102c on its upper portion 102a is not essential. The stopper 102 may be constructed in a configuration shown in Figure 48. As shown in Figure 48, the stopper 102 further includes an intermediate diameter middle portion 102d located between  
15 the larger diameter upper portion 102a and the smaller diameter lower portion 102b. The middle portion 102d is configured such that its peripheral surface is fittingly received by the inner face of the open end of the outer tubular container 101. The inner face of the open end of  
20 the inner tubular container 2 is designed to fittingly receive the peripheral surface of the lower portion 102b.

The degree of the aforementioned pressure reduction is selected such that blood can be introduced immediately into the interior of tubular container 2 when a blood-collecting  
25 needle is at one end inserted into a patient's blood vessel

and at another end inserted through the stopper 102. In general, the tubular containers 2 and 101 are reduced in internal pressure to about 0.1 - 0.9 atmospheric pressure.

5 The outer tubular container 101 can be formed from suitable materials such as synthetic resins and glasses, preferably from transparent materials, as analogous to those used to form the above-described inner tubular container 2.

10 The material used to form the stopper 102 is not particularly specified, and may be a natural or synthetic rubber having rubber elasticity, such as silicone or butyl rubber.

For blood test containers 81, 90 and 100 respectively shown in Figures 42, 46 and 47, the sliding switch 83 is set at the highest position during collection of blood 6 and centrifugation, as shown in Figures 49(a), 50(a) and 51(a). Preferably, the blood 6 is collected such that a blood level A does not reach the lower edge 3a of the test reagent 3, for the purpose of preventing the contact of the blood 6 and the test reagent 3. The subsequent centrifuging causes the blood 6 to separate into the serum or plasma 6a and the blood clot or cell 6b, as respectively shown in Figures 49(b), 50(b) and 51(b). After centrifugation, the sliding switch 83 is moved downwardly to contact a part of the test reagent 3 with the serum or plasma 6a for determination of components present therein. For the blood test container

100 shown in Figure 47, the outer tubular container 101 is removed before the sliding switch 3 is moved downwardly.

The centrifuging may be performed at 500 - 5,000 r.p.m. for about 3 - 30 minutes, preferably at 500 - 3,000 r.p.m. for about 5 - 25 minutes.

Figures 42, 46 and 47 show that a pair of test reagents 3, 3 are provided facing toward each other. However, the test reagent 3 may be singularly provided in a single location.

Exemplary constructions of a blood test container in accordance with the invention as recited in claims 24 - 26 will be now described with reference to Figures 53 through 55.

Figure 53 is a transverse sectional view of a blood test container as recited in claim 24. For this blood test container 111, a second tubular container 112 having a closed bottom is accommodated within a closed-bottom tubular container 2 having a larger diameter than the second tubular container 112. The second tubular container 112 has a hole 112a at its bottom. A cover member 113, in the form of a water-soluble membrane, is secured to the bottom of the second tubular container 112 to close the hole 112a.

The test reagents 3, 3 are secured either to an outer face of the second tubular container 112 or to an inner face of the tubular container 2. The blood test reagents 3, 3

may be secured to the outer face of the second tubular container 112, although they are shown in Figure 53 as being secured to the inner face of the tubular container 2.

Those materials used to form the tubular container, second tubular container and blood test reagent for the invention as recited in claim 12 can also be utilized to form the above-described tubular container 2, second tubular container 112 and blood test reagent 3, respectively.

The stopper 5 is further provided to close the tubular container 2.

The stopper 5 can be formed from suitable materials such as rubber and synthetic resins.

The material of the water-soluble membrane used to form the cover member 113 is not particularly specified, so long as it can be solubilized by a water content in blood, serum or plasma. Examples of materials which can form the water-soluble membrane include natural polymers, semisynthetic materials and synthetic polymers. Examples of natural polymers include chitin, chitosan, casein, collagen, egg albumin, starch, seaweeds, carrageenan, sodium alginate, agar, xanthane gum, pullulan and the like.

Examples of semisynthetic materials include dextrin, methyl cullulose, carboxy methyl cellulose and the like.

Examples of synthetic polymers include polyvinyl alcohol, sodium polyacrylate, polymethacrylic acid,

polyacrylamide, polyethylene oxide, polyethylene glycol and the like.

Exemplary commercial products usable to form the water-soluble membrane include SOLUBLON, name used in trade and manufactured by Daicel Chemical Co., Ltd.; KURAREAR, name used in trade and manufactured by Kuraray Co., Ltd.; TOSLON, name used in trade and manufactured by Tokyo Cellophane Co., Ltd.; HI-CELLON, name used in trade and manufactured by Nippon Synthetic Film Co., Ltd.; VINYLON Film, name used in trade and manufactured by Kuraray Co., Ltd.; BOBLON, name used in trade and manufactured by Nippon Synthetic Film Co., Ltd.; EXCEED, name used in trade and manufactured by Okura Kogyo Co., Ltd.; EVAL, name used in trade and manufactured by Kuraray Co., Ltd.; and the like.

When in use, blood is introduced into the second tubular container 112. In an initial condition, the blood is held staying in the second tubular container 112 and thus its contact with the blood test reagent 3, 3 is prevented. That is, the cover member 113 that closes the hole 112a functions to prevent the blood under the initial condition from contacting the blood test reagent.

With the lapse of time, an increasing fraction of the cover member 113 dissolves into the water content of the blood to finally allow the blood to flow into a space between the outer face of the second tubular container 112

and the inner face of the tubular container 2 and reach the blood test reagents 3, 3, whereby a reaction thereof is caused to proceed.

5 The reaction results can be observed visually from outside, or alternatively, measured by a suitable measuring equipment such as a spectro photometer, reflected light reading equipment or camera.

10 The serum or plasma may be brought into contact with the blood test reagents 3, 3, after the blood has been introduced into the second tubular container 112 and then centrifuged. In this case, the cover member 113 is solubilized by the water content in the serum or plasma to allow the serum or plasma to flow into the space defined between the outer face of the second tubular container 112 and the inner face of the tubular container 2 and then  
15 contact the blood test reagents 3, 3.

While centrifuged, the blood test container 111 may be maintained in the orientation as shown in Figure 53. Alternatively, the blood test container 111 while  
20 centrifuged may be maintained in the reversed orientation and then turned upside down after the centrifuging.

The aforementioned stopper 5 may be attached to the tubular container 2. The subsequent reduction in internal pressure of the tubular container 2 and second tubular  
25 container 112 will then allow the blood to be introduced

into the second tubular container 112 by a vacuum blood-collecting technique.

By the use of the blood test container 111 shown in Figure 53, the determination of components in the blood can  
5 be efficiently accomplished while a chance for a tester to contact blood during a period from collection of the blood until test results are obtained is effectively reduced.

Particularly when a vacuum blood-collecting technique is employed, a chance for an examiner to contact blood  
10 during a whole process starting from blood collection and ending with attainment of test results is further reduced. The employment of this technique is thus desirable.

Figure 54 is a sectional view, illustrating a blood test container 121 in accordance with the invention as  
15 recited in claim 25. This blood test container 1 is identical in construction to the blood test container 111 shown in Figure 53, with the exception that the hole 112a pierced in a bottom of the second tubular container 112 is closed by a cover member 122 formed of a metal. The cover  
20 member 122 is positioned to close an inner face side of the hole 112a. Due to the presence of the cover member 122, the blood introduced into the second tubular container 112 is prevented from passing through the hole 112a into the tubular container 2.

25 In the measurement, the cover member 122 may be moved

to open the hole 112a by using an external magnet. That is, a magnetic force is utilized to move the cover member 122 to open the hole 112a. Then, the blood introduced or the serum or plasma centrifugally separated therefrom is allowed to  
5 flow into the space defined between the inner face of the tubular container 2 and the outer face of the second tubular container 112. The measurement can thus be carried out in the same manner as for the blood test container 111 shown in Figure 53.

10 Preferably, paramagnetic materials, such as iron and nickel, whose motion is controllable by a magnet, are used to form the cover member 122.

Alternatively, the cover member 122 itself may be formed from a magnet. In such a case, a motion of the cover  
15 member 122 can be controlled by an external metal plate formed of paramagnetic material, such as an iron plate.

Figure 55 is a sectional view which explains a blood test container 131 in accordance with the invention as recited in claim 26.

20 In this embodiment, the blood test reagent 3 is secured onto an inner face of the tubular container 2. The blood test reagent 3 surface is exposed only at its bottom region 3a adjacent a bottom end, and its remaining surface region is covered with a protective layer 132.

25 The blood test reagent 3 can be secured onto an inner

face of the tubular container 2 by an arbitray method, such as by using an adhesive or pressure-sensitive adhesive. Any material can be used to form the protective layer 132 which serves to prevent contact of the blood test reagent 3 with  
5 blood, so long as it can actually prevent the contact of the blood test reagent 3 with the blood. Suitable materials include glass, synthetic resins such as polyeethylene terephthalate, and the like. Preferably, the protective layer is rendered tranparent so that visual observation of  
10 changes of the blood test reagent from outside is permitted.

The cover layer 132 is positioned to leave only the reaction-initiating bottom region 3a uncovered and cover all surfaces of the remaining region of the blood test reagent 3.

15 In the measurement, blood or blood component, after being introduced into the tubular container 2, is left at rest. In this case, only the bottom region 3a of the blood test reagent 3 is immersed in the blood or blood component to initiate a reaction.

20 For the blood test container 131 shown in Figure 55, only a part of the blood test reagent is immersed in the blood or its component and a major part of the blood test reagent 3 is prevented from being wetted.

Exemplary constructions of a blood test container 141  
25 in accordance with the invention as recited in claims 9 and

10 are now specifically described with reference to Figures 56(a) and 56(b) - Figures 58(a) and 58(b).

For the blood test container 141 shown in Figure 56(a), the aforementioned contact control structure is positioned within the tubular container 2 and an inner tube 142 formed of a flexible resin is further provided. An outer surface portion of the inner tube 142 is brought into close contact with an inner face of the tubular container 2. However, an upper portion of the inner tube 142 is configured to have a declining diameter toward its top end, i.e., have an outer diameter smaller than an inner diameter of the tubular container 2 so that a peripheral surface of the inner tube 142 upper portion is spaced from the inner face of the tubular container 2.

A communicating member 143 is provided in the space defined between the inner face of the tubular container 2 and the peripheral surface of the inner tube 142 such that it is moveable in a length direction of the tubular container 2. The form of the communicating member 143 is not particularly specified, so long as it is permitted to move in the length direction of the tubular container 2. The communicating member may be provided in the form of beads, an annular ring or the like.

The inner tube 142 can be made from various materials, so long as it is made flexible and its lower portion can be

brought into close contact with the inner surface of the tubular container 2. Examples of suitable materials include polypropylene, polyethylene, soft vinyl chloride, nylon, polyurethane foam and the like. In the case of a thin-wall inner tube, polyethylene terephthalate, polycarbonate, rigid vinyl chloride and the like can also be used, for example. In such a case, the wall thickness of the inner tube 142 may preferably be selected such that its lower portion is made flexible and elastic sufficient to be brought into close contact with the inner face of the tubular container 2.

The material used to form the communicating member 143 is not particularly specified, so long as it permits the member to move in the length direction of the tubular container 2. Useful materials include suitable glasses, metals and synthetic resins such as nylon, polypropylene and polyethylene terephthalate.

For the blood test container 141, the blood test reagent 3 is secured onto an inner face of the tubular container 2. The blood test reagent 3 used in the invention shown in Figures 1 and 2 can also be used for the blood test reagent 3 in this embodiment. The technique used for securement is not particularly specified.

The blood test reagent 3 must be secured in a position above a bottom end of the tube 142 portion which is held in close contact with the inner face of the tubular container

2. This is purposed to prevent the contact of the blood introduced with the blood test reagent 5 by locating the blood inside the contact region of the inner tube 142 and tubular container 2 and placing the blood test reagent 5 outside the contact region.

For the blood test container 1 shown in Figure 56, a separating medium 144 is accommodated in the tubular container 2 to reside at its bottom portion. The separating medium 144 can be comprised of materials suitable for the separation of serum or plasma from solid matter, respective produced when blood is centrifuged, and may be comprised principally of chlorinated polybutene (Patent Laying-Open No. Sho 55-43462), a modified oligomer of cyclopentadiene (Patent Laying-Open No. Hei 2-95257),  $\alpha$ -olefin·maleic diester copolymer (Patent Laying-Open No. Sho 57-149964) or the like, for example. It will be recognized that the separating medium is not necessarily accommodated in the tubular container.

Also, the stopper 5 is mounted to the tubular container 2. After mounting of the stopper 5, an interior of the tubular container 2 may preferably be reduced in pressure so that blood can be introduced into the tubular container 2 by a vacuum blood-collecting technique.

In the measurement, the blood 6 is introduced into the tubular container 2, as shown in Figure 56(b). In this

instance, a projector needle may be inserted through the stopper 5 to supply the blood 6 into the tubular container. Alternatively, the blood 6 may be introduced into the inner tube 142 by a vacuum blood-collecting technique.

5           Although the blood 6 is introduced inside of the inner tube 142, the close contact of the inner tube 142 with the tubular container 2 prevents the blood 6 from passing across the contact region into the space between the peripheral surface portion of the inner tube 142 and the inner face of  
10 the tubular container 2. The contact of the blood 6 with the blood test reagent 3 is thus inhibited.

          When left at rest for a certain period, the blood 6 is coagulated to separate into serum 6A and clot 6B, as shown in Figure 57(a). The blood test container 141 is thereafter  
15 turned upside down and then centrifuged. As a result, the separating medium layer 144 is caused to move to a position of intermediate height, whereby the clot 6B is completely isolated from the serum 6A, as shown in Figure 57(b). Concurrently, the communicating member 143 is caused to move  
20 downward, so that the contact area of the inner tube 142 and tubular container 2 is reduced.

          When the centrifugation is repeated, the communicating member 143 is caused to move further downward. In this instance, the downward movement of the communicating member  
25 143 results in the formation of a clearance between the

peripheral surface of the inner tube 142 and the inner face of the tubular container 2, as shown in figures 58(a) and (b). The serum 6A separated is then allowed to pass through the clearance into the space, defined between the the outer  
5 face of the inner tube 142 and the inner face of the tubular container 2, where it contacts the blood test reagent 3 and a reaction therebetween is allowed to proceed.

In the situation shown in Figure 58(b), the communicating member 143 has already fallen onto the  
10 separating medium layer 144 and the outer face of the inner tube 142 has been brought again into close contact with the inner face of the tubular container 2. However, the reaction in the blood test reagent 3 is sustained.

Accordingly, the reaction results can be observed  
15 visually from outside, or alternatively, measured by a suitable measuring equipment such as a spectro photometer and a camera, as described earlier.

For the blood test container shown in Figure 56 - Figure 58, there hardly exists a chance for a tester to  
20 contact blood because a whole process from blood collection till acquisition of measurement results is performed within the tubular container 2. This accordingly results in the safe and efficient measurement of the blood or blood components.

25 A blood test container in accordance with the invention

as recited in claim 11 will be now described with reference to Figure 59 - Figure 61.

For a blood test container 151 shown in Figure 59(a), a closed-bottom inner tube 152 is disposed such that a portion adjacent its open top end is held in close contact with an inner face of the tubular container 2. Those materials used to form the inner tube 142 of the blood test container 141 shown in Figure 58 can also be used for the inner tube 152.

In the illustrated construction, a lower portion of the inner tube 152 is configured to have a reducing diameter, that is, its bottom-adjacent portion has a reduced outer diameter. Accordingly, a peripheral surface of the bottom-adjacent portion of inner tube 152 is spaced from an inner face of the tubular container 2. The communicating member 143 is placed within the space between the peripheral surface of the inner tube 152 and the inner face of the tubular container 2.

The blood test reagent 3 is secured to an inner face of the inner tube 152 at a position below a top end of the contact region where the inner tube 152 is held in close contact with the tubular container 2.

The blood test container 151 shown in Figure 59 is identical in construction to the blood test container shown in Figure 56, excepting the arrangement and configuration of the inner tube 152 and the arrangement of the communicating

member and blood test reagent 5.

In the measurement, the blood 6 is introduced into the tubular container 2, as shown in Figure 59(b). In this instance, because the top-adjacent portion of the inner tube 5 152 is held in close contact with the inner face of the tubular container 2, the blood 6 introduced is prevented from flowing into a space in which the communicating member 143 and the blood test reagent 3 are accommodated, i.e., prevented from flowing into a space outside the contact 10 region where the inner tube 152 is held in close contact with the inner face of the tubular container 2. In an initial condition, the contact of the blood 6 with the blood test reagent 6 can thus be prevented.

When left to stand for a certain period, the blood 6 is 15 coagulated to separate into serum 6A and clot 6B (shown in Figure 60(a)).

The blood test container 151 is thereafter turned upside down and then centrifuged. As a result, the serum 6A is completely isolated from the clot 6B by the separating 20 medium layer 144, as shown in Figure 60(b). Since this centrifugation is performed under mild conditions, the communicating member 143 is allowed to stay above the contact region where the inner face of the tubular container 2 is held in close contact with the outer face of the tube 25 152.

When the centrifugation is repeated, the communicating member 143 is caused to move downward. As shown in Figures 61(a) and 61(b), the downward movement of the communicating member 143 results in releasing the contact of the outer surface of the inner tube 152 with the inner surface of the tubular container 2. This permits the serum 6A to flow into the space defined outside the inner tube 3 and contact the blood test reagent 3, whereby a reaction thereof is allowed to proceed.

In the situation shown in Figure 61(b), the communicating member 143 has already fallen to bring the outer face of the inner tube 142 into contact with the inner face of the tubular container 2. However, the above-described reaction is sustained because the blood test reagent has already contacted the serum 6A.

Therefore, the reaction result can be observed or measured from outside in the same manner as in the case for the blood test container 141 shown in Figure 56.

## DESCRIPTION OF EXAMPLES

Specific examples of the present invention will be now described.

### (EXAMPLE 1)

A blood test container 1 as shown in Figure 1 was assembled. A serum separating medium-containing vacuum

blood-collecting tube (manufactured by Sekisui Chemical Co., Ltd., product name: INSEPACK, a 15mm diameter and 100 mm long polyethylene terephthalate tube having an inner wall surface coated with a blood coagulation promoter) was  
5 provided. A rubber stopper was removed from the vacuum blood-collecting tube to bring its interior to a normal pressure, thereby constituting a tubular container 2.

A strip of test paper was removed from a reaction container incorporating a single dosage QUICK CHASER HBsAg  
10 (manufactured by Mizuho Meddy Co., Ltd., about 6 cm long reagent for HBs antigen detection) to use as a detection reagent 3. The detection reagent was adhesively secured to the tubular container by using a pressure-sensitive adhesive tape such that its top end is located 8 cm above a bottom 2b  
15 of the tubular container.

The HBs antigen detection reagent (QUICK CHASER HBsAg) is an immunochromatography assay reagent based in principle on a sandwich technique. When a blood sample contacts a lower portion of the reagent, the sample blood is caused to  
20 migrate on the reagent according to a capillary phenomenon. The HBs antigen present in the blood sample reacts with anti-HBs mouse monoclonal antibody binding colloidal gold to form an HBs antigen-antibody-colloidal gold complex. This complex further migrates on a membrane filter to reach the  
25 anti-HBs mouse monoclonal antibody solid phase portion where

it is bound trapped. As a result, in the case of HBs antigen positive, a red purple line derived from the colloidal gold is caused to appear in the solid phase portion, but not in the case of HBs antigen negative.

5 Whether HBs antigen positive or negative can thus be visually determined.

Blood was injector collected from human subjects A, B and C. 7 ml of each sample blood collected was transferred into the blood test container of the present Example which  
10 was left to stand for 10 minutes. Each sample blood was then centrifuged at 3,000 r.p.m. for 10 minutes by using a centrifugal separator (manufactured by a domestic company, product name: H-20). As a result, the blood was separated into serum 6a and solid matter 6b (refer to Figure 3(b)).

15 After centrifuged, the container was left to stand for 10 minutes. The serum 6a was thereafter contacted with the reagent 3. The results proved HBs antigen negative for all the subjects, A, B and C.

(EXAMPLE 2)

20 A blood test container 4 as shown in Figure 4 was assembled. That is, the rubber stopper was removed from the serum separating medium-containing vacuum blood-collecting tube used in Example 1 to prepare a tubular container 2, the reagent 3 was secured within the tubular container 2 in the  
25 same manner as in Example 1, and the rubber stopper 5 was

attached at 0.26 atmospheric pressure by using a vacuum  
capping machine VS-150A (manufactured by Kyowa Shinku, Co.,  
Ltd.) to obtain the blood test container 4, as shown in  
Figure 4, which carried the stopper 5 and was constructed to  
5 permit vacuum collection of 7 ml blood.

By using this blood test container 4, blood samples  
were collected for evaluation from the subjects A, B and C  
in the same manner as in Example 1. The results proved HBs  
antigen negative for all blood samples from the subjects, A,  
10 B and C.

(EXAMPLE 3)

A blood test container 7 as shown in Figure 5 was  
assembled. The rubber stopper was removed from the vacuum  
blood-collecting tube used in Example 1 to prepare a tubular  
15 container 2. A cone-shaped polyethylene container (having  
an inner wall surface coated with a blood coagulation  
promoter) having a maximum diameter of 15 mm, a minimum  
diameter of 6 mm and a thickness of 0.1 mm, as an inner  
tubular portion 8, was inserted into the tubular container  
20 2. A 6 mm diameter polystyrene bead (manufactured by  
Sekisui Chemical Co., Ltd., product name: POLYSTYRENE BEAD  
#45), as a solid member 9, was adhesively secured to a  
bottom end of the inner tubular portion 8.

A conjugate liquid attached to a single-dosage HBs  
25 antigen detection reagent (product name: DYNASCREEN HBsAg,

manufactured by Dynabbot Co., Ltd.) was dropped by the amount of 50  $\mu$ l onto an upper end of a reagent plate to prepare a test reagent 3 which was subsequently secured to an inner wall of the tubular container 2 by using a  
5 pressure-sensitive adhesive tape.

The blood test container 7 such assembled was used to collect blood samples from the subjects A - C in the same manner as in Example 1. Each sample blood was left at rest for 10 minutes and then centrifuged at 3,000 r.p.m. for 10  
10 minutes by using a centrifugal separator (manufactured by a domestic company, product name: H-20). As a result, the solid member 9 was forced to fall while the blood was caused to separate into serum and clot. After the centrifuging, the container was left to stand for 10 minutes. Example 1  
15 was then followed to subsequently contact the serum with the test reagent 3, which resulted in proving HBs antigen negative for all the subjects, A, B and C.

(EXAMPLE 4)

A blood test container 7 as shown in Figure 6 was  
20 assembled. In addition to the HBs antigen detection reagent, an HBs antibody detection reagent (manufactured by Dynabbot Co., Ltd., product name: single dosage DYNASCREEN O-SUB) was further secured to the blood test container 7 assembled in Example 3. The rubber stopper was attached at  
25 0.26 atmospheric pressure by using a vacuum capping machine

(manufactured by Kyowa Shinku, Co., Ltd., product name: VS-150A) to permit vacuum collection of 7 ml blood. By using the blood test container thus obtained, evaluation was made in the same manner as in Example 3 resulting in proving HBs antigen negative and HBs antibody negative for all the subjects A - C.

(EXAMPLE 5)

A blood test container 10 as shown in Figure 7 was assembled. In the same manner as in Example 1, a rubber stopper was removed from the serum separating medium-containing vacuum blood-collecting tube (manufactured by Sekisui Chemical Co., Ltd., product name: INSEPACK) to bring its interior to a normal pressure, thereby preparing a tubular container 2. A 6 mm diameter and 60 mm long polypropylene tube (having an inner wall surface coated with a blood coagulation promoter) was used to constitute a second tubular container 11. A 5  $\mu$ m pore-size filter was removed from MILLEX-SV, manufactured by Millipore Co., Ltd., and cut to provide a 10 mm diameter porous plate which was then secured onto a bottom face of the second tubular container 11 by a pressure-sensitive adhesive tape.

The HBs antigen detection reagent and HBs antibody detection reagent, same in type as those used in Example 4, were then secured onto an inner wall surface of the tubular container 2 in the same manner as in Example 1. Thereafter,

the second tubular container 11 was adhesively secured to a bottom face of the stopper which was subsequently attached to the tubular container 2 for insertion of the second tubular container therein.

5           The second tubular container may be directly secured to the inner face of the tubular container as by using an adhesive or a bridge.

10           The blood test container 10 such assembled was used to collect blood samples from the subjects A - C in the same manner as in Example 1. Each sample blood was left at rest for 10 minutes, centrifuged at 3,000 r.p.m. for 10 minutes by using a centrifugal separator (manufactured by a domestic company, product name: H-20) and then left to stand for 10 minutes. The visual observation of the reagents through a  
15           container outer wall led to proving HBs antigen negative and HBs antibody negative for all the subjects A - C.

(EXAMPLE 6)

20           An interior of the tubular container 2 of the blood test container as prepared in Example 5 was reduced in pressure to provide a blood test container 10 shown in Figure 8. In this instance, pressure reduction was achieved by using a vacuum capping machine (manufactured by Kyowa Shinku, Co., Ltd., product name: VS-150A) which placed the rubber stopper on the container at 0.85 atmospheric pressure  
25           to permit vacuum collection of 1 ml blood.

The blood test container such assembled was used to collect blood samples from the subjects A - C. After left to stand for 10 minutes, each sample blood was centrifuged in the same manner as in Example 5. As a result, each blood sample separated into serum 6a and clot 6b, as shown in Figure 10(b). Subsequent to the centrifuging, each container was left to stand for 10 minutes to observe the reagents 3. The results proved HBs antigen negative and HBs antibody negative for all the subjects A - C.

(EXAMPLE 7)

A blood test container 13 shown in Figure 11 was assembled. The serum separating medium-containing vacuum blood-collecting tube used in Example 1 was utilized for a tubular container 2.

The stopper was removed from the tubular container 2 to bring its interior to a normal pressure.

A 6 mm diameter and 60 mm long polypropylene tube (having an inner wall coated with a blood coagulation promoter) was used for a tubular member 14. A rubber was removed from a top end of a piston incorporated in a 5 ml syringe, manufactured by Nipro Co., Ltd., and centrally apertured by a cutter to provide an annular member 15 having a centrally-located, 6 mm diameter through-hole.

Then, the HBs antigen detection reagent and HBs antibody detection reagent 3, 3 were secured onto an inner

wall surface of the tubular container 2 in the same manner as in Example 4.

A top end of the tubular member 14 was adhesively secured to a bottom face of the stopper and the annular member 15 was attached to the tubular member 14. The stopper was then attached to the tubular container 2 for insertion of those members thereinto, thereby obtaining a blood test container 13. The blood test container 13 such assembled was used to collect blood samples from the subjects A - C in the same manner as in Example 1. After left to stand for 10 minutes, each blood sample was centrifuged at 3,000 r.p.m. for 10 minutes by a centrifugal separator (product of a domestic centrifuge manufacturer, product name: H-20). Subsequent to the centrifuging, each container was left to stand for 10 minutes to observe the reagents 3, 3. The results proved HBs antigen negative and HBs antibody negative for all the subjects A - C.

The annular member 15 may be secured to the tubular container as by a bridge.

(EXAMPLE 8)

A blood test container 13 shown in Figure 12 was assembled. That is, in the assembly of the blood test container 13 in Example 7, the attachment of the stopper 5 was accomplished by a vacuum capping machine (manufactured by Kyowa Shinku, Co., Ltd., product name: VS-150A) which

placed the rubber stopper on the container at 0.26  
atmospheric pressure to permit vacuum collection of 7 ml  
blood.

5 The blood test container 13 such assembled was used to  
vacuum collect blood samples from the subjects A - C. As a  
result, the blood 6 was introduced into the tubular member  
14 and reached a bottom surface of the annular member 15, as  
shown in Figure 14(a). After left to stand for 10 minutes,  
each blood sample was centrifuged at 3,000 r.p.m. for 10  
10 minutes by a centrifugal separator (product of a domestic  
centrifuge manufacturer, product name: H-20). This caused  
the blood to separate into serum 6a and clot 6b and also  
forced the annular member 15 to move upward to a position of  
intermediate height, as shown in Figure 14(b). After left  
15 to stand for 10 minutes, the reagents 3 were observed for  
each container. The results proved HBs antigen negative and  
HBs antibody negative for all blood samples from the  
subjects A - C.

(EXAMPLE 9)

20 A blood test container 16 shown in Figure 15 was  
assembled. A tubular container 2 was prepared by removing  
the stopper from the serum separating medium-containing  
vacuum blood-collecting tube used in Example 1 to bring its  
interior to a normal pressure.

25 A second tubular container 17 was prepared by securing

a porous plate, as fabricated according to the below-described procedure, by adhesive to a bottom of a 6 mm diameter and 60 mm long polypropylene tube (having an inner wall coated with a blood coagulation promoter).

5           That is, a 10  $\mu$ m porous-size filter was removed from MILLEX-SV, name used in trade and manufactured by Millipore Co., Ltd., and cut to a diameter of 10 mm to provide the aforementioned porous plate. This porous plate was secured by a pressure-sensitive adhesive tape onto an open bottom of  
10 the polypropylene tube.

The test reagent 3, identical in type to that used in Example 4, was secured onto an inner wall of the tubular container 2 in the same manner as in Example 4.

A second tubular container 17 was adhesively secured to  
15 a bottom end of the stopper which was subsequently attached to the tubular container 2 for insertion of the second tubular container thereinto.

By using the blood test container 16 thus obtained, blood samples were collected from the subjects, A - C, left  
20 to stand for 10 minutes, cetrifuged and evaluated in the same manner as in Example 1. After the centrifugation, each container was left to stand for 10 minutes to subsequently observe its reagent 3. Results proved HBs antigen negative and HBs antibody negative for all the subjects A - C.

25           The porous plate may be secured to the tubular

container by adhesives or a bridge.

(EXAMPLE 10)

A blood test container 16 shown in Figure 16 was assembled. That is, in the assembly of the blood test container 16 in Example 9, the attachment of the stopper 5 was accomplished by a vacuum capping machine (manufactured by Kyowa Shinku, Co., Ltd., product name: VS-150A) which placed the rubber stopper on the container at 0.26 atmospheric pressure to permit vacuum collection of 7 ml blood. Other than the above, the procedure of Example 9 was followed.

Blood samples were collected from the subjects, A - C, by using the blood test container above obtained. As shown in Figure 18(a), each blood sample 6 was introduced into the second tubular container 17. After the lapse of 10 minutes, each blood sample was centrifuged at 3,000 r.p.m. for 10 minutes. By this centrifuging, each blood sample, while separated into serum 6a and clot 6b, was forced to flow from the second tubular container 17 into the tubular container 2. After centrifugation, the container was left to stand for 10 minutes to subsequently observe its reagents 3. The results proved HBs antigen negative and HBs antibody negative for all the subjects A - C.

(EXAMPLE 11)

A blood test container 18 shown in Figure 19 was

assembled. The tubular container 2 was analogous to that used in Example 1. A 6 mm diameter and 98 mm long polypropylene tube (having an inner wall coated with a blood coagulation promoter) was used for a tubular member 19. The  
5 test reagent 3, identical in type to that used in Example 4, was secured to an inner wall of the tubular container 2 in the same manner as in Example 4.

A rubber stopper originally incorporated in the tubular container 2 was used for a cap 20. The tubular member 19  
10 was adhesively secured to a bottom face of the cap which was subsequently placed on the tubular container 2 for insertion of the tubular member therein.

Next, a blood sample from each of the subject, A - C, was collected in the blood test container 18, as analogously  
15 to Example 1, left to stand for 10 minutes and centrifuged in the same manner as in Example 1. After centrifugation, each container was left to stand for 10 minutes to subsequently observe its reagents 3. The results proved HBs antigen negative and HBs antibody negative for all the  
20 subjects A - C.

It will be recognized that the tubular member 19 may be secured to the tubular container as by a bridge.

(EXAMPLE 12)

For the blood test container used in Example 11, an  
25 interior of its tubular container 2 was reduced in pressure

so that blood can be vacuum collected therein. That is, for the attachment of the rubber stopper 5 to which the tubular container 19 was adhesively secured, as shown in Figure 20, a vacuum capping machine (manufactured by Kyowa Shinku, Co., Ltd., product name: VS-150A) was utilized which placed the rubber stopper 5 on the container at 0.26 atmospheric pressure to permit vacuum collection of 7 ml blood.

Next, the blood test container was used to vacuum collect blood from each of the subjects, A - C, in the same manner as in Example 2. As a result, the blood 6 was introduced into the tubular member 19, as shown in Figure 22(a). In this instance, no fraction of the blood 6 was found to leak from a bottom end of the tubular member 19 toward the interior of the tubular container 2. With the lapse of 10 minutes, each blood sample was centrifuged in the same manner as in Example 11. As a result, each blood sample, while separated into serum 6a and clot 6b, leaked from the tubular member 19 to the tubular container 2 side, as shown in Figure 22(b). After centrifugation, each container was left to stand for 10 minutes to observe the reagents 3, resulting in proving HBs antigen negative and HBs antibody negative for all the blood samples from the subjects A - C.

(EXAMPLE 13)

A blood test container 22 shown in Figure 23 was

assembled. The tubular container 2 was analogous to that used in Example 1. A 6 mm diameter and 60 mm long polyethylene tube, as a tubular member 23, was adhesively secured onto an inner wall surface of the tubular container 2 such that a top end of the polyethylene tube was located 10 mm below a top end of the tubular container 2. A 6 mm diameter polystyrene bead (manufactured by Sekisui Chemical Co., Ltd., product name: POLYSTYRENE BEAD #45) was secured by adhesive to a bottom of the tubular member 23.

The test reagent 3, identical in type to that used in Example 1, was secured within the polystyrene tube in the same manner as in Example 1. The elevation of the reagent 3 was adjusted such that its bottom end is located 8 cm above the bottom end of the tubular container 2.

Next, a blood sample from each of the subjects, A - C, was collected in the tubular container 2, as analogously to Example 1, while avoiding its entry into the tubular member 23. After left to stand for 10 minutes, each blood sample was centrifuged in the same manner as in Example 1. The centrifuging was found to cause the polystyrene bead, as a solid member 24, to fall and the blood to separate into serum and clot. Also, the serum was found to enter the tubular member 23.

After centrifugation, each container was left to stand for 10 minutes. The observation of the reagent 3 resulted

in proving HBs antigen negative for all the blood samples from the subjects A - C.

(EXAMPLE 14)

A blood test container 22 shown in Figure 24 was  
5 assembled. Specifically, the configuration of the blood test container 22 shown in Figure 23 was followed, except that the tubular container 2 fixedly accommodated therein two tubular members 23 to which two types of reagents 3, 3, identical to those used in Example 4, were respectively  
10 secured, and that its interior was reduced in pressure. For pressure reduction, a vacuum capping machine (manufactured by Kyowa Shinku, Co., Ltd., product name: VS-150A) was utilized which placed the rubber stopper 5 on the container at 0.26 atmospheric pressure to permit vacuum collection of  
15 7 ml blood.

A blood sample was collected from each of the subjects, A - C, by using the blood test container thus prepared and evaluated in the same manner as in Example 13. The results proved HBs antigen negative and HBs antibody negative for  
20 all the blood samples from the subjects A - C.

(EXAMPLE 15)

A blood test container 31 shown in Figure 25 was assembled. The serum separating medium-containing vacuum blood-collecting tube used in Example 1 was used for the  
25 tubular container 2.

A rubber stopper was removed from this tubular container 2 to bring its interior to a normal pressure.

Also, a 6 mm diameter and 60 mm long polypropylene tube (having an inner wall coated with a blood coagulation promoter) was used for a tubular member 14. A rubber was removed from a top end of a piston incorporated in a 5 ml syringe, manufactured by Nipro Co., Ltd., and centrally apertured by a cutter to provide an anuular member 15 having a centrally-located, 6 mm diameter through-hole.

10 The anuular member was immersed in diicosane, the temperature of which was controlled at 50 °C. Then, the anuular member was taken out from the diicosane, and the anuular member was fixed to the outer surface of the tubular member 14 and inserted in the tubular container 2, so that  
15 the anuular member 15 was secured through diicosane to the outer face of the tubular member 14 and the inner face of the tubular container 2.

Then, the HBs antigen detection reagent 3 was secured onto an inner wall surface of the tubular container 2 in the  
20 same manner as in Example 4.

Thereafter, the rubber stopper was adhesively secured onto a top end of the tubular member 14 and then pressed to fit in the tubular container 2. This results in obtaining the blood test container 31.

25 By using the blood test container 31 such assembled, a

blood sample was collected from each of the subjects, A - C, in the same manner as in Example 1. After left to stand for 10 minutes, each blood sample was centrifuged at 3000 r.p.m. for 10 minutes by a cetrifuge. As a result, the sample  
5 blood separated into serum 6a and solid matter 6b. Each container was placed in the 50 °C bath for 10 minutes. The subsequent dissolution of diicosane allowed the serum 6a to push the annular member 15 upward and finally contact the test reagent 3. The observation of the reagent 3 revealed  
10 HBs antigen negative and HBs antibody negative for all the the subjects A - C.

(EXAMPLE 16)

A blood test container 31 shown in Figure 26 was assembled in such a configuration as to permit vacuum  
15 collection of blood. Specifically, in the assembly of the blood test container 31 in Example 15, the attachment of the stopper 5 was accomplished by a vacuum capping machine (manufactured by Kyowa Shinku, Co., Ltd., product name: VS-150A) which placed the rubber stopper on the container at  
20 0.26 atmospheric pressure to permit vacuum collection of 7 ml blood.

By using the blood test container 31 such assembled, a blood sample was collected from each of the subjects, A - C. After left to stand for 10 minutes, each blood sample was  
25 centrifuged in the same manner as in Example 15 and then

maintained at 50 °C for 10 minutes.

Due conceivably to the dissolution of diicosane, the serum 6a pushed the annular member 15 upward and finally contacted the test reagent 3 in the same fashion as in Example 15. The observation of the reagent 3 resulted in proving HBs antigen negative and HBs antibody negative for all the blood samples from the subjects A - C.

(EXAMPLE 17)

A blood test container 41 shown in Figure 29 was assembled in the following manner. The tubular container 2, identical in configuration to that of Example 1, was used. As analogous to Example 1, QUICK CHASER HBsAg (manufactured by Mizuho Meddy Co., Ltd., about 6 cm long reagent for HBs antigen detection) was used for the test reagent 3. This test reagent was secured onto an inner wall of the tubular container 2 by a pressure-sensitive adhesive tape such that its top end is located 8 cm above a bottom 2b of the tubular container.

A polyethylene terephthalate test tube (manufactured by Sekisui Chemical Co., Ltd., 12 mm in diameter and 95 mm in length, having an inner wall coated with a blood coagulation promoter) was used for a second tubular container 42.

The second tubular container 42 was inserted in the tubular container 2 with the test reagent 3 secured thereon, which was subsequently closed by a stopper 5 formed of butyl

bromide rubber.

The stopper 5 was removed, a blood sample from each of the subjects, A - C, was collected by an injector, and 1 ml of each blood sample collected was injected into the second tubular container 42 for the blood test container 41 of the present Example.

After injection, the stopper 5 was again attached to the blood test container. The blood test container was turned upside down and left to stand for 30 minutes during which period the blood sample was contacted with the test reagent 3. The observation of the test reagent 3 resulted in proving HBs antigen negative for all the subjects A - C.

(EXAMPLE 18)

A blood test container was assembled in the same manner as in Example 17, with the exception that the test reagent 3 was secured to an outer face of the second tubular container 42 such that its top end was located 7 cm above the bottom of the second tubular container 42, but not secured to the inner face of the tubular container 2.

For the blood test container such assembled, the second tubular container 42 carrying the test reagent on its outer surface was inserted into the outer tubular container 2. The stopper used in Example 17 was then placed on the outer tubular container at 0.9 atmospheric pressure by a vacuum capping machine (manufactured by Kyowa Shinku, Co., Ltd.,

product name: VS-150A), which made it possible for the container to vacuum collect 1 ml blood.

5 A blood sample from each of the subjects, A - C, was brought in the second tubular container 42 according to a conventional vacuum blood collection procedure. After left to stand for 10 minutes, each blood sample was centrifuged at 3,000 r.p.m. for 10 minutes by using a centrifuge (product of a domestic manufacturer, product name: H-20). Thereafter, the blood test container was turned upside down  
10 to introduce the separated serum into a space defined between the inwardly-located second tubular container and the outer tubular container. This reversed orientation was maintained for 30 minutes during which time the test reagent was contacted with the serum. The observation of the test  
15 reagent resulted in proving HBs antigen negative for all the subjects A - C.

(EXAMPLE 19)

The following procedure was used to assemble a blood test container which was identical in construction to the  
20 blood test container 43 shown in Figure 30, with the exception that the test reagent 3 was fixedly positioned on the outer face of the second tubular container 42. The tubular container 2 was identical in construction to that used in Example 1.

25 Used for the second tubular container 42 was a serum

separating medium-containing vacuum blood-collecting tube  
(manufactured by Sekisui Chemical Co., Ltd., product name:  
INSEPACK, a 12 mm diameter and 75 mm long polyethylene  
terephthalate tube having an inner wall coated with a blood  
5 coagulation promoter).

The HBs antigen detection reagent used in Example 1, as  
the test reagent 3, was adhesively secured onto the outer  
face of the second tubular container 42 such that its top  
end was located 7 cm above the bottom of the second tubular  
10 container 42.

The second tubular container 42 with the test reagent 3  
adhesively secured on its outer face was inserted in the  
tubular container 2. A 5 mm wide and 20 mm long water-  
soluble film (pullulan), as the water-soluble material, was  
15 then secured around an outer periphery of the second tubular  
container 42 adjacent its top opening by an instantaneous  
adhesive (manufactured by Toa Gosei Co., Ltd., product name:  
ALONE-ALFA), so that the space X between the second tubular  
container 42 and tubular container 2 was closed.

20 Further, the butyl bromide rubber stopper 5 was placed  
on the tubular container 2 at 0.9 atmospheric pressure by a  
vacuum capping machine (manufactured by Kyowa Shinku, Co.,  
Ltd., product name: VS-150A), which made it possible for the  
container to vacuum collect 1 ml blood.

25 A blood sample from each of the subjects, A - C, was

brought in the second tubular container 42 according to a conventional vacuum blood collection procedure. After left to stand for 10 minutes, each blood sample was centrifuged at 3,000 r.p.m. for 10 minutes by using a centrifuge

5 (product of a domestic manufacturer, product name: H-20). Thereafter, the blood test container was turned upside down to introduce the separated serum into a space defined between the inwardly-located second tubular container and the outer tubular container. This reversed orientation was  
10 maintained for 30 minutes during which time the test reagent was contacted with the serum. The observation of the test reagent resulted in proving HBs antigen negative for all the subjects A - C.

(EXAMPLE 20)

15 The procedure of Example 19 was followed, except that, instead of using the water-soluble film "pullulan", diicosane was coated around the outer periphery of the second tubular container 42 adjacent its top opening to close the space X defined between the second tubular container 42 and tubular  
20 container 2. As a result, a blood test container 43 was assembled.

Also, a stopper was placed on the above-obtained blood test container in the same manner as in Example 19, which made it possible for the container to vacuum collect 1 ml  
25 blood.

A blood sample from each of the subjects, A - C, was collected in the second tubular container 42 of the above-obtained blood test container according to a vacuum blood collection technique. After left to stand for 10 minutes, 5 each blood sample was centrifuged in the same manner as in Example 19. Next, the blood test container 43 was turned upside down and then placed in a constant temperature bath (manufactured by Komatsu Electronics Co., Ltd., product name: CTE24-A) controlled at 50 °C to reside therein for 30 10 minutes. The observation of the test reagent 3 resulted in proving HBs antigen negative for all the subjects A - C.

(EXAMPLE 21)

The following procedure was used to assemble the blood test container 45 shown in Figure 31. The tubular container 15 2 was identical in construction to that used in Example 1.

Used for the tubular container 42 was a serum separating medium-containing vacuum blood-collecting tube (manufactured by Sekisui Chemical Co., Ltd., product name: INSEPACK, a 12 mm diameter and 75 mm long polyethylene 20 terephthalate tube having an inner wall coated with a blood coagulation promoter). Also, a 2.5 mm wide, 5 mm long and 0.5 mm deep groove 42a was provided on the inner face of the second tubular container 42 to extend downwardly from its top opening.

25 Further provided was a butyl bromide rubber stopper 46

which had a vertically-extending 2.5 mm wide, 5 mm long and 0.5 mm deep groove 46c on its first stopper portion 46a.

5 The test reagent 3, identical to the HBs antigen detection reagent used in Example 1, was adhesively secured onto the outer face of the second tubular container 42 in the same manner as in Example 18.

10 The second tubular container 42 with the test reagent 3 adhesively secured thereon was inserted in the tubular container 2. The butyl bromide rubber stopper was then placed on the second tubular container, with its groove 46c displaced from longitudinal alignment with the groove 42a, at 0.9 atmospheric pressure by a vacuum capping machine (manufactured by Kyowa Shinku, Co., Ltd., product name: VS-150A), which made it possible for the container to vacuum  
15 collect 1 ml blood.

A blood sample from each of the subjects, A - C, was introduced into the second tubular container 42 according to a vacuum blood collection technique. After left to stand for 10 minutes, each blood sample was centrifuged at 3,000  
20 r.p.m. for 10 minutes by using a centrifuge (product of a domestic manufacturer, product name: H-20). Then, the blood test container 45 was turned upside down and the stopper 46 was rotated to align the groove 46c with the groove 42a thereby providing a flow path. As a result, the separated  
25 serum was introduced into the space X between the second

tubular container 42 and the tubular container 2. After left to stand for 30 minutes, the test reagent 3 was observed. The results proved HBs antigen negative for all the subjects A - C.

5 (EXAMPLE 22)

The tubular container 2 and second tubular container 42 used in Example 20 were utilized. Also, the HBs antigen detection reagent, as the test reagent 3, was adhesively secured onto the outer face of the second tubular container 42 in the same manner as in Example 20.

Subsequently, the second tubular container 42 with the test reagent 3 adhesively secured thereon was inserted in the tubular container 2. 0.2 g of serum separating medium was removed from a separately-provided, serum separating medium-containing vacuum blood-collecting tube (manufactured by Sekisui Chemical Co., Ltd., product name: INSEPACK) and then coated around the outer periphery of the second tubular container 42 to close the space X between the second tubular container 42 and tubular container 2.

20 The butyl bromide rubber stopper 5 was utilized, as analogously to Example 20, to assemble the blood test container 43 in such a configuration as to permit vacuum collection of 1 ml blood. A blood sample from each of the subjects, A - C, was brought in the second tubular container 42 according to a conventional vacuum blood collection

procedure. After left to stand for 10 minutes, each blood sample was centrifuged at 3,000 r.p.m. for 10 minutes by using a centrifuge (product of a domestic manufacturer, product name: H-20). Then, the blood test container was  
5 turned upside down to introduce the separated serum into a space between the inwardly-located second tubular container and the outer tubular container. This reversed orientation was maintained for 30 minutes during which time the test reagent 3 was contacted with the serum. The subsequent  
10 observation of the test reagent resulted in proving HBs antigen negative for all the subjects A - C.

(EXAMPLE 23)

The tubular container 2 and second tubular container 42 used in Example 19 were utilized. Also, the HBs antigen  
15 detection reagent, as the test reagent 3, was adhesively secured onto the outer face of the second tubular container 42 in the same manner as in Example 19.

After its top opening was sealed by a polymer film 52 comprised of a parafilm, the second tubular container 42 was  
20 inserted in the tubular container 2.

Also, the butyl bromide rubber stopper 5 was placed on the tubular container by using a vacuum capping machine, as analogously to Example 19, which made it possible for the container to vacuum collect 1 ml blood. As a result, the  
25 blood test container 51 was assembled.

A blood sample from each of the subjects, A - C, was brought in the second tubular container 42 according to a conventional vacuum blood collection procedure. After left to stand for 10 minutes, each blood sample was centrifuged at 3,000 r.p.m. for 10 minutes by using a centrifuge (product of a domestic manufacturer, product name: H-20). Then, the blood test container was turned upside down to introduce the separated serum into a space between the inwardly-located second tubular container and the outer tubular container. This reversed orientation was maintained for 30 minutes during which time the test reagent 3 was contacted with the serum. The subsequent observation of the test reagent resulted in proving HBs antigen negative for all the subjects A - C.

(EXAMPLE 24)

The procedure of Example 23 was followed, except that the parafilm used to constitute the polymer film 52 was replaced by a film-form diicosane, to assemble the blood test container 51 in such a configuration as to permit vacuum collection of 1 ml blood.

A blood sample from each of the subjects, A - C, was vacuum collected in the second tubular container 42 of the above-assembled blood test container. After left to stand for 10 minutes, each blood sample was centrifuged in the same manner as in Example 19. Subsequently, the blood test

container 43 was turned upside down and placed in a constant temperature bath (manufactured by Komatsu Electronics Co., Ltd., product name: CTE24-A) controlled at 50 °C to reside therein for 30 minutes. The subsequent observation of the test reagent 3 resulted in proving HBs antigen negative for all the subjects A - C.

(EXAMPLE 25)

The following procedure was used to assemble the blood test container 61 shown in Figure 37. The tubular container 2 used in Example 1 was utilized.

In fabricating the second tubular container 62, a SANPREP filter (manufactured by Millipore Co., Ltd., product number: MILLEX-LH, pore size of 0.5  $\mu$ m) was attached to a top end of a 2.5 ml blood-collecting syringe (manufactured by Terumo Co., Ltd.), 0.4 g of polystyrene gel having a particle size of 8  $\mu$ m (manufactured by Sekisui Chemical Co., Ltd., product name: MICRONEX) was introduced into the syringe from its upper portion (i.e., through an opening for insertion of a piston), and a 1.5 ml polypropylene sample cup (manufactured by Eppendorf Co., Ltd.) was embedded centrally of the aforementioned gel to constitute the trap portion 62a while constituting the blood cell separating layer 62b from the gel.

Next, the HBs antigen detection reagent used in Example 1, as the test reagent 3, was adhesively secured onto the

inner face of the tubular container 2.

The second tubular container 62, as fabricated in the manner as described above, was secured to a bottom of the stopper 5 by using an instantaneous adhesive (manufactured by Toa Gosei Co., Ltd., product name: ALONE-ALFA) and then inserted in the tubular container 2, followed by placement of the stopper on the tubular container 2.

A blood sample from each of the subjects, A - C, was collected by an injector. 1 ml of each blood sample was transferred to the blood test container of the present Example and then centrifuged at 3,000 r.p.m. for 10 minutes by using a centrifuge (product of a domestic manufacturer, product name: H-20).

After centrifugation, the blood test container was left to stand for 10 minutes. The subsequent observation of the reagent secured on the container wall resulted in proving HBs antigen negative for every subject.

(EXAMPLE 26)

The blood test container 61 was assembled in the same manner as in Example 25. However, the stopper 5 was placed on the second tubular container 62 at 0.85 atmospheric pressure by a vacuum capping machine (manufactured by Kyowa Shinku, Co., Ltd., product name: VS-150A), which made it possible for the container to vacuum collect 1 ml blood.

A blood sample from each of the subjects, A, B and C,

was collected in the blood test container of the present Example and then centrifuged at 3,000 r.p.m. for 10 minutes by using a centrifuge (product of a domestic manufacturer, product name: H-20). After centrifugation, each blood test  
5 container was left to stand for 10 minutes. The subsequent observation of the reagent on the container wall resulted in proving HBs antigen negative for all the three subjects.

(EXAMPLE 27)

The following procedure was used to assemble the blood  
10 test container 71 shown in Figure 39. The tubular container 2 used in Example 1 was utilized.

The rubber stopper was removed from the tubular container 2 to bring its interior to a normal pressure.

A 6 mm diameter and 60 mm long polypropylene tube  
15 (having an inner wall coated with a blood coagulation promoter) was used for the second tubular container 72.

A filter, manufactured by Millipore Co., Ltd. (product number: MILLEX-SV, pore size of 5  $\mu$ m), was cut to a diameter of 10 mm and then secured to a bottom opening of the second  
20 tubular container 72 by using a pressure-sensitive adhesive tape. In this manner, a bottom member 72b comprised of the aforementioned filter was secured to the bottom end of the second tubular container 72.

0.2 g of polystyrene gel having a particle size of 8  $\mu$ m  
25 (manufactured by Sekisui Chemical Co., Ltd., product name:

MICRONEX) was then charged into the second tubular container 72 to form therein the hydrophilic fine particle layer 73.

Thereafter, the HBs antigen detection reagent, as the test reagent 3, was adhesively secured onto the inner face of the tubular container 2 in the same manner as in Example 1.

The second tubular container 72 was secured to a bottom of the stopper 5 by an instantaneous adhesive (manufactured by Toa Gosei Co., Ltd., product name: ALONE-ALFA) and then inserted inserted in the tubular container 2, followed by placement of the stopper on the tubular container 2. A blood sample from each of the subjects, A, B and C, was brought in the second tubular container 72 according to a conventional vacuum blood collection procedure. After left to stand for 10 minutes, each blood sample was centrifuged at 3,000 r.p.m. for 10 minutes by a centrifuge (product of a domestic manufacturer, product name: H-20). Then, the blood test container was turned upside down to introduce the separated serum into a space between the inwardly-located second tubular container and the outer tubular container. This reversed orientation was maintained for 30 minutes during which time the test reagent 3 was contacted with the serum. The subsequent observation of the test reagent 3 resulted in proving HBs antigen negative for the subjects A, B and C.

## (EXAMPLE 28)

The procedure of Example 27 was followed, except that the stopper 5 was placed on the tubular container at 0.85 atmospheric pressure by using a vacuum capping machine  
5 (manufactured by Kyowa Shinku, Co., Ltd., product name: VS-150A), to assemble the blood test container 71 (shown in Figure 39) capable of vacuum collecting 1 ml blood.

By using the blood test container thus assembled, a blood sample from each of the subjects, A, B and C, was  
10 collected and evaluated in the same manner as in Example 27. Ther results proved HBs antigen negative and HBs antibody negative for all the blood samples from the subjects A - C.

## (EXAMPLE 29)

Whole blood was used for each specimen in this Example.

15 The blood test container 4 shown in Figure 4 was assembled. A blood coagulation inhibitor-containing vacuum blood-collecting tube (manufactured by Sekisui Chemical Co., Ltd., product name: INSEPACK, a 15 mm diameter and 100 mm long polyethylene terephtalate tube having an inner wall  
20 uncoated with a blood coagulation promoter) was provided. A rubber stopper was removed from this vacuum blood-collecting tube to bring its interior to a normal pressure, thereby obtaining the tubular container 2.

Next, a single-dosage QUICK CHASER HBsAg (manufactured  
25 by Mizuho Meddy Co., Ltd., about 6 cm long reagent for HBs

antigen detection), as the test reagent 3, was adhesively secured onto the tubular container by a pressure-sensitive adhesive tape such that its top end was located 8 cm above the bottom 2b of the tubular container.

5           Subsequently, the stopper 5 was placed on the tubular container at 0.26 atmospheric pressure by using a vacuum capping machine (manufactured by Kyowa Shinku, Co., Ltd., product name: VS-150A) to assemble the blood test container 4 with the stopper 5, as shown in Figure 4, in such a  
10 configuration as to permit vacuum collection of 7 ml blood.

By using the blood test container thus assembled, a blood sample from each of the subjects, A - C, was collected and left at rest for 10 minutes. The subsequent observation of the test reagent 3 resulted in proving HBs antigen  
15 negative for all the blood samples from the subjects A - C.

(EXAMPLE 30)

The following procedure was used to assemble the blood test container 41B shown in Figure 40. The tubular container 2 used in Example 1 (but uncoated on its inner  
20 wall surface with a blood coagulation promoter) was utilized. 1 ml of 0.04 wt.% solution of Bromothymol Blue indicator (manufactured by Wako Pure Pharm. Co., Ltd.), as the test reagent 3b, was charged in the tubular container.

A rubber stopper was removed from a plasma separating  
25 medium-containing vacuum blood-collecting tube (manufactured

by Sekisui Chemical Co., Ltd., a 12 mm diameter and 95 mm long tube having an inner wall uncoated with a blood coagulation promoter) to bring its interior to a normal pressure, thereby providing the second tubular container 42.

5 This second tubular container 42 was then inserted in the tubular container 2 accommodating therein the aforementioned test reagent 3b, followed by placement of the butyl bromide rubber stopper 5 on the outer tubular container 2 at 0.26 atmospheric pressure by using a vacuum capping machine  
10 (manufactured by Kyowa Shinku, Co., Ltd., product name: VS-150A). As a result, the blood test container 41B with the stopper 5, as shown in Figure 40, was assembled in such a configuration as to permit vacuum collection of 7 ml blood.

A blood sample from each of the subjects, A, B and C,  
15 was brought in the second tubular container 42 according to a conventional vacuum blood collection procedure. Each blood sample was then centrifuged at 3,000 r.p.m. for 10 minutes by a centrifuge (product of a domestic manufacturer, product name: H-20). Then, the blood test container was  
20 turned upside down to introduce the separated plasma into a space between the inwardly-located second tubular container and the outer tubular container. This reversed orientation was maintained for 30 minutes during which time the test reagent 3b was contacted with the plasma. The test reagent  
25 was subsequently observed. The Bromothymol Blue indicator

solution was found as having turned in color to green, i.e., having been neutralized, for the subjects A, B and C.

(EXAMPLE 31)

The following procedure was used to assemble the blood  
5 test container 41C shown in Figure 41. The tubular  
container 2 used in Example 1 (but uncoated on its inner  
wall surface with a blood coagulation promoter) was  
utilized. 1 mg of powder-form Bromothymol Blue indicator  
(manufactured by Wako Pure Pharm. Co., Ltd.), as the test  
10 reagent 3c, was introduced into the tubular container.

A rubber stopper was removed from a plasma separating  
medium-containing vacuum blood-collecting tube (manufactured  
by Sekisui Chemical Co., Ltd., a 12 mm diameter and 95 mm  
long tube having an inner wall uncoated with a blood  
15 coagulation promoter) to bring its interior to a normal  
pressure, thereby providing the second tubular container 42.  
This second tubular container 42 was then inserted in the  
tubular container 2 accommodating therein the aforementioned  
test reagent 3c, followed by placement of the butyl bromide  
20 rubber stopper 5 on the outer tubular container 2 at 0.26  
atmospheric pressure by using a vacuum capping machine  
(manufactured by Kyowa Shinku, Co., Ltd., product name: VS-  
150A). As a result, the blood test container 41C with the  
stopper 5, as shown in Figure 40, was assembled in such a  
25 configuration as to permit vacuum collection of 7 ml blood.

A blood sample from each of the subjects, A, B and C, was brought in the second tubular container 42 according to a conventional vacuum blood collection procedure. Each blood sample was then centrifuged at 3,000 r.p.m. for 10 minutes by a centrifuge (product of a domestic manufacturer, product name: H-20). Then, the blood test container was turned upside down to introduce the separated plasma into a space between the inwardly-located second tubular container and the outer tubular container. This reversed orientation was maintained for 30 minutes during which time the test reagent was contacted with the plasma. The test reagent was subsequently observed. The Bromothymol Blue indicator was found as having turned in color to green, i.e., having been neutralized, for the subjects A, B and C.

(EXAMPLE 32)

The blood test container 90A shown in Figure 52(a) was assembled. The blood test container 90A was identical in construction to the blood test container 90 shown in Figure 46, excepting the below-described difference.

Difference: For the blood test container 90, the tube 91 was adhesively secured onto the bottom surface of the lid member 92. On the other hand, for the blood test container 90A, the tube 91 was adhesively secured to the rubber stopper 5 for attachment to the tubular container 2.

First, a rubber stopper was removed from a plasma

separating medium-containing vacuum blood-collecting tube  
(manufactured by Sekisui Chemical Co., Ltd., product name:  
INSEPACK, a 10 mm diameter and 75 mm long polyethylene  
terephthalate tube) to bring its interior to a normal  
5 pressure, thereby providing the tubular container 2.

A pair of opposing rectangularly-shaped slots 2f, 2f,  
each having a width of 3 mm and a length of 30 mm, were  
provided which extend downwardly from a open top edge along  
a side wall of the tubular container 2. The sliding switch  
10 83 (made from polyethylene and having 5 mm wide and 10 mm  
long outer wing 83a and inner wing 83b) was attached to each  
slot 2f such that its outer wing 83a and inner wing 83b  
flanked therebetween the opposing side walls 2g, 2h (refer  
to Figure 43) of the slot 2f therebetween.

15 A single-dosage QUICK CHASER HBsAg (manufactured by  
Mizuho Meddy Co., Ltd., 5 mm wide and 40 mm long reagent for  
HBs antigen detection), as the test reagent 3, had been  
previously suspended from a top end of the joining member  
83c of the sliding switch 83, with the aid of a pressure-  
20 sensitive adhesive tape, such that when the sliding switch  
83 was shifted to the highest position, a top edge of the  
test reagent 3 was located 60 mm above the bottom of the  
tubular container 2.

The aforementioned HBs antigen detection reagent (QUICK  
25 CHASER HBsAg) is an immunochromatography assay reagent based

in principle on a sandwich technique. When a blood sample is contacted with a lower portion of the reagent, the blood sample is caused to migrate on the reagent according to a capillary phenomenon. The HBs antigen present in the blood sample then reacts with the anti-HBs mouse monoclonal antibody binding colloidal gold, as previously coated on the reagent, to form an HBs antigen-antibody-colloidal gold complex. This complex further migrates on a membrane filter to reach the anti-HBs mouse monoclonal antibody solid phase portion where it is bound trapped. As a result, in the case of HBs antigen positive, a red purple line derived from the colloidal gold is caused to appear in the solid phase portion, but not in the case of HBs antigen negative. Whether HBs antigen positive or negative can thus be visually determined.

The 6 mm diameter and 60 mm long polypropylene tube 91 was at its top end secured to a bottom of the stopper 5 (i.e., a rubber stopper used in the vacuum blood-collecting tube, INSEPACK), sized to fit in the above-described tubular container 2, by an adhesive (manufactured by Toa Gosei Co., Ltd., product name: Alone-alfa). The stopper 5 carrying the tube 91 adhesively secured thereto was then fittingly placed at the top opening of the tubular container 2 to which the sliding switches 83 were attached. As a result, the blood test container 90A was assembled.

A blood sample was collected from each of the subjects, A, B and C, by an injector, and its blood-collecting needle was thrust through the stopper 5 of the above-obtained blood test container to introduce 1 ml of each blood sample into the blood test container (refer to Figure 52(a)). Each blood sample was centrifuged at 3,000 r.p.m. for 10 minutes by using a centrifuge (product of a domestic manufacturer, product name: H-20), and as a result, separated into plasma 6A and hemocyte 6B.

After centrifugation, the sliding switch 83 was pushed down to bring a part of the test reagent 3 into contact with the plasma 6A (refer to Figure 52(b)). After left to stand for 10 minutes, the test reagent 3 was observed. The results proved HBs antigen negative for all the subjects, A, B and C.

(EXAMPLE 33)

The blood test container 100 shown in Figure 51 was assembled. Specifically, a rubber stopper was removed from a vacuum blood-collecting tube identical in construction to that used in Example 32 to provide the tubular container 2. A pair of sliding switches 83 each carrying the test reagent 3 were attached to the tubular container 2 in the same manner as in Example 32. The test reagent 3 secured to the sliding switch 83 on one slot 2f was identical in type to the test reagent 3 (QUICK CHASER HBsAg) used in Example 32.

However, the test reagent 3 secured to the sliding switch 83 on the other slot 2f was the HBs antibody detection reagent (manufactured by Dynabbot Co., Ltd., product name: DYNASCREEN O-SUB), instead of QUICK CHASER HBsAg.

5           A top end of the tube 91 identical in construction to that used in Example 32 was adhesively secured onto a bottom surface of the stopper 102 sized to fit in the top opening of the tubular container 2 and having the groove 102c. The stopper 102 carrying the tube 91 adhesively secured thereon  
10 was then fitted in the top opening of the tubular container 2 bearing the pair of sliding switches 83.

Next, a 13 mm diameter and 100 mm long, closed-bottom tubular container 101, formed of polyethylene terephthalate, was put lightly to cover the tubular container 2, followed  
15 by pressing the open top edge of the tubular container 101 into the groove 102c of the stopper 102 at 0.85 atmospheric pressure by using a vacuum capping machine (manufactured by Kyowa Shinku, Co., Ltd., product name: VS-150A). As a result, the shown blood test container was assembled in such  
20 a configuration as to permit vacuum collection of 1 ml blood.

The blood test container such assembled was set at a holder for vacuum blood collection, to which a multiple blood-collecting needle had been attached. This multiple  
25 blood-collecting needle was at its one end stuck into a

blood vessel of a human subject and at its another end thrust through the stopper 102. According to such a conventional vacuum blood collection procedure, 1 ml of a blood sample was collected from each of the human subjects, A, B and C. Each blood sample was centrifuged at 3,000 r.p.m. for 10 minutes by using a centrifuge (product of a domestic manufacturer, product name: H-20), and as a result, separated into plasma 6A and hemocyte 6B.

After centrifugation, the outer tubular container was removed and then the sliding switch 83 was pushed down to bring a part of the test reagent 3 into contact with the plasma 6A (refer to Figure 51(b)). After left to stand for 10 minutes, the test reagent 3 was observed. The results proved HBs antigen negative and HBs antibody negative for all the subjects, A, B and C.

(EXAMPLE 34)

The blood test container 111 shown in Figure 53 was assembled. A 15.5 mm diameter and 100 mm long, polyethylene terephthalate tubular container 2 (manufactured by Sekisui Chemical Co., Ltd., product name: SEPARAPIT TUBE) and a 6 mm diameter and 85 mm long, polyethylene terephthalate second tubular container 112 (manufactured by Sekisui Chemical Co., Ltd., product name: SEPARAPIT TUBE) were provided. An interior of each of the tubular container 2 and second tubular container 112 was washed with purified water.

Next, a bottom of the second tubular container 112 was apertured to provide a 3 mm diameter hole 112a.

QUICK CHASER HBsAg ((manufactured by Mizuho Meddy Co., Ltd., 6 cm long reagent for HBs antigen detection), as the test reagent 3, was secured onto an outer wall of the second tubular container by a pressure-sensitive adhesive tape. In this instance, the blood test reagent 3 was secured such that its top edge was located 1 cm above the bottom opening of the second tubular container.

5 mg of EDTA, as the anti-coagulant, was introduced into the second tubular container 112.

The second tubular container 112 was then inserted in the tubular container 2 which was subsequently closed by the stopper 5.

A blood sample from each of the subjects, A, B and C, was collected by an injector. 2 ml of each blood sample collected was injected into the blood test container of the present Example which was subsequently left to stand for 40 minutes. The following observation of the blood test reagent 3 resulted in proving HBs antigen negative for all the blood samples from the subjects, A, B and C.

(EXAMPLE 35)

The blood test container 111 shown in Figure 53 was assembled. A 15.5 mm diameter and 100 mm long, polyethylene terephthalate tubular container 2 (manufactured by Sekisui

Chemical Co., Ltd., product name: SEPARAPIT TUBE) and a 6 mm diameter and 85 mm long, polyethylene terephthalate second tubular container 112 (manufactured by Sekisui Chemical Co., Ltd., product name: SEPARAPIT TUBE) were provided. An  
5 interior of each of the tubular container 2 and second tubular container 112 was washed with purified water.

Next, a bottom of the second tubular container 112 was apertured to provide a 3 mm diameter hole 112a.

QUICK CHASER HBsAg ((manufactured by Mizuho Meddy Co.,  
10 Ltd., 6 cm long reagent for HBs antigen detection), as the blood test reagent, was secured onto an outer wall of the second tubular container 112 by using a pressure-sensitive adhesive tape. In this instance, the blood test reagent 3 was secured such that its top edge was located 1 cm above  
15 the bottom opening of the second tubular container 112.

2 mg of EDTA, as the anti-coagulant, was introduced into the second tubular container 112.

The second tubular container 112 such treated was then inserted in the tubular container 2, followed by placement  
20 of the stopper 5 on the outer tubular container at 0.56 atmospheric pressure by using a vacuum capping machine (manufactured by Kyowa Shinku, Co., Ltd., product name: VS-150A). As a result, the blood test container of the present Example was assembled in such a configuration as to permit  
25 vacuum collection of 2 ml blood.

The blood test container such assembled was used to vacuum collect a blood sample from each of the subjects, A, B and C. Each blood test container was then left to stand for 40 minutes. The subsequent observation of the blood test reagent 3 resulted in proving HBs antigen negative for all the blood samples from the subjects, A, B and C.

(EXAMPLE 36)

The blood test container 121 shown in Figure 54 was assembled. A 15.5 mm diameter and 100 mm long, polyethylene terephthalate tubular container 2 (manufactured by Sekisui Chemical Co., Ltd., product name: SEPARAPIT TUBE) and a 6 mm diameter and 85 mm long, polyethylene terephthalate second tubular container 112 (manufactured by Sekisui Chemical Co., Ltd., product name: SEPARAPIT TUBE) were provided. An interior of each of the tubular container 2 and second tubular container 112 was washed with purified water.

Next, a bottom of the second tubular container 112 was apertured to provide a 3 mm diameter hole 112a. A water-soluble cover member comprised of a 6 mm diameter disc-form water-soluble film (pullulan) was secured by instantaneous adhesive (manufactured by Toa Gosei Co., Ltd., product name: ALONE-ALFA) to cover and close the hole 112a.

QUICK CHASER HBsAg ((manufactured by Mizuho Meddy Co., Ltd., 6 cm long reagent for HBs antigen detection), as the blood test reagent 3, was secured onto an outer wall of the

second tubular container 112 by using a pressure-sensitive adhesive tape. In this instance, the blood test reagent 3 was secured such that its top edge was located 1 cm above the bottom opening of the second tubular container 112.

5           5 mg of EDTA, as the anti-coagulant, was introduced into the second tubular container 112.

Next, the second tubular container 112 was inserted in the tubular container 2 which was subsequently closed by the stopper 5.

10           A blood sample from each of the subjects, A, B and C, was collected by an injector. 2 ml of each blood sample collected was injected into the blood test container of the present Example which was subsequently left to stand for 40 minutes. The following observation of the blood test  
15 reagent 3 resulted in proving HBs antigen negative for all the blood samples from the subjects, A, B and C.

(EXAMPLE 37)

The blood test container 121 shown in Figure 54 was assembled. A 15.5 mm diameter and 100 mm long, polyethylene  
20 terephthalate tubular container 2 (manufactured by Sekisui Chemical Co., Ltd., product name: SEPARAPIT TUBE) and a 6 mm diameter and 85 mm long, polyethylene terephthalate second tubular container 112 (manufactured by Sekisui Chemical Co., Ltd., product name: SEPARAPIT TUBE) were provided. An  
25 interior of each of the tubular container 2 and second

tubular container 112 was washed with purified water.

Next, a bottom of the second tubular container 112 was apertured to provide a 3 mm diameter hole 112a. A water-soluble cover member comprised of a 6 mm diameter disc-form water-soluble film (pullulan) was secured by instantaneous adhesive (manufactured by Toa Gosei Co., Ltd., product name: ALONE-ALFA) to cover and close the hole 112a.

QUICK CHASER HBsAg ((manufactured by Mizuho Meddy Co., Ltd., 6 cm long reagent for HBs antigen detection), as the blood test reagent 3, was secured onto an outer wall of the second tubular container 112 by using a pressure-sensitive adhesive tape. In this instance, the blood test reagent 3 was secured such that its top edge was located 1 cm above the bottom opening of the second tubular container 112.

2 mg of EDTA, as the anti-coagulant, was introduced into the second tubular container 112.

The second tubular container 112 such treated was then inserted in the tubular container 2, followed by placement of the stopper 5 on the outer tubular container at 0.56 atmospheric pressure by using a vacuum capping machine VS-150A (manufactured by Kyowa Shinku, Co., Ltd.). As a result, the blood test container of the present Example was assembled in such a configuration as to permit vacuum collection of 2 ml blood.

The blood test container such assembled was used to

vacuum collect a blood sample from each of the subjects, A, B and C. Each blood test container was then left to stand for 40 minutes. The subsequent observation of the blood test reagent 3 resulted in proving HBs antigen negative for all the blood samples from the subjects, A, B and C.

(EXAMPLE 38)

The procedure of Example 36 was followed, except that the cover member 122 comprised of a 4 mm diameter stainless steel plate was brought into contact with the inner face of the hole 112a to close the hole 112a, to assemble the blood test container.

2 mg of EDTA, as the anti-coagulant, was introduced into the second tubular container 112, and then a blood sample was collected from each of the subjects, A, B and C, in the same manner as in Example 36.

The stainless steel cover member 122 was then caused to shift by moving a magnet outside the blood test container to open the hole 112a, which allowed each blood sample to flow into the space defined between the tubular container 2 and the second tubular container 112 and contact the blood test reagent 3.

Each blood test container was left to stand for 40 minutes and then its blood test reagent 3 was observed. The results proved HBs antigen negative for all the blood samples from the subjects, A, B and C.

## (EXAMPLE 39)

The blood test container 121 shown in Figure 54 was assembled in the same manner as in Example 38. However, after insertion of the second tubular container 112 in the tubular container 2, the stopper 5 was placed on the outer tubular container at 0.56 atmospheric pressure by using a vacuum capping machine VS-150A (manufactured by Kyowa Shinku, Co., Ltd.). As a result, the blood test container was assembled in such a configuration as to permit vacuum collection of 2 ml blood.

Thereafter, the cover member 122 was caused to shift by moving the external magnet, which allowed each blood sample to flow from an interior of the second tubular container 112 into the space between the tubular container 2 and second tubular container 112, where it was contacted with the blood test reagent 3.

## (EXAMPLE 40)

The blood test container 131 shown in Figure 55 was assembled. A 15.5 mm diameter and 100 mm long, polyethylene terephthalate tubular container 2 (manufactured by Sekisui Chemical Co., Ltd., product name: SEPARAPIT TUBE) was provided. An interior of this tubular container 2 was washed with purified water.

A single-dosage of QUICK CHASER HBsAg (manufactured by Mizuho Meddy Co., Ltd., 6 cm long reagent for HBs antigen

detection), as the test reagent 3, was secured onto an inner wall of the tubular container 2 with the aid of a pressure-sensitive adhesive tape. An upper portion of the blood test reagent 3 was covered with a protective layer, in the form  
5 of a polyethylene terephthalate film (3 cm wide and 6 cm long), to leave its lower 1 cm length portion uncovered. In this case, the protective layer 132 was secured to a surface of the blood test reagent 3 by a pressure-sensitive adhesive tape.

10           5 mg of EDTA, as the anti-coagulant, was introduced into the tubular container 131 which was subsequently closed by the stopper 5.

A blood sample was collected by an injector from each of the subjects, A, B and C. 2 ml of each blood sample  
15 collected was injected into the blood test container of the present Example which was subsequently left to stand for 40 minutes. The following observation of the blood test reagent 3 resulted in proving HBs antigen negative for all the blood samples from the subjects, A, B and C.

20           (EXAMPLE 41)

The blood test container 131 shown in Figure 55 was assembled in the same manner as in Example 40. However, the stopper 5 was placed on the tubular container at 0.56  
atmospheric pressure by using a vacuum capping machine VS-  
25 150A (manufactured by Kyowa Shinku, Co., Ltd.). As a

result, the blood test container was assembled in such a configuration as to permit vacuum collection of 2 ml blood.

Thereafter, a blood sample from each of the subjects, A, B and C, was vacuum introduced into the above-assembled blood test container which was subsequently left to stand for 40 minutes. The subsequent observation of the blood test reagent 3 resulted in proving HBs antigen negative for all the blood samples from the subjects, A, B and C.

#### 10 UTILITY IN INDUSTRY

For the blood test container according to the present invention, the blood test reagent is secured within the closed-bottom tubular container. Therefore, blood test results can be immediately obtained by (1) introducing blood or its component into the blood test container where it is allowed to contact the blood test reagent, or alternatively, (2) introducing the blood into the blood test container and centrifuging whereby its component, such as serum or plasma, is allowed to the blood test container.

Conventional blood test methods have required complex procedure involving collecting and centrifuging the blood to separate out the serum or plasma, and taking it up and transferring dropwise onto a reagent by using a dropping pipet. This has also imposed a risk for a tester to contact

25

the blood. In contrast, the use of the blood test container according to the present invention not only simplifies the blood test procedure but also substantially eliminates the risk for a tester to contact the blood. This assures the efficient and safe blood testing.

The invention as recited in claim 2 further includes the contact control structure effective to normally prevent the contact of blood introduced into the tubular container with the test reagent and, when centrifuged, allow a component of the blood to contact the test reagent. This arrangement permits the efficient and safe testing, as well as assuring contact of serum or plasma alone with the test reagent leading to the increased accuracy of blood testing.

In accordance with the invention as recited in claim 3, the aforementioned contact control structure is configured to include the inner container portion and the solid member. Accordingly, the blood introduced into the inner tubular container, prior to being centrifuged, is blocked by the solid member to stay within an interior of the inner container portion and prevented from contacting the test reagent. When centrifuged, the solid member is forced to fall down to allow the then separated serum or plasma to successfully contact the test reagent secured onto the inner face of the tubular container and/or the outer face of the inner container portion.

In accordance with the invention as recited in claim 4, the contact control structure is configured to include the tubular member accommodated in the tubular container and the annular member. Accordingly, when introduced into the  
5 tubular member, the blood is initially restricted by the annular member from flowing toward the test reagent. When centrifuged, the blood is forced to move from the tubular member toward the tubular container while pushing up the annular member, so that the then separated serum or plasma  
10 is allowed to successfully reach and contact the test reagent.

In accordance with the invention as recited in claim 5, the contact control structure is configured to include a tubular member accommodated in the tubular container and  
15 having a bottom end brought into contact with an interior bottom face of the tubular container, and a pressing means for pressing the tubular member against the interior bottom face of the tubular container so that the blood introduced into the tubular member is prevented from leaking therefrom.  
20 Accordingly, when introduced into the tubular member, the blood is prevented from leaking therefrom toward the tubular container. When centrifuged, the blood, while separated into serum or plasma and solid matter, is forced to escape toward the tubular container where the separated serum or  
25 plasma is allowed to successfully contact the test reagent.

In accordance with the invention as recited in claim 6,  
the contact control structure is configured to include the  
tubular member secured onto the inner face of the tubular  
container, the test reagent fixedly accommodated in the  
5 tubular member, and the solid member located below the test  
reagent and designed to fall down when centrifuged.

Accordingly, when introduced into the tubular container, the  
blood is prevented from flowing into the tubular member.

When subsequently centrifuged, the solid member is forced to  
10 fall down while the blood is separated into serum or plasma  
and solid matter, so that the serum or plasma is permitted  
to easily flow into the tubular member for contact with the  
test reagent.

In accordance with the invention as recited in claim 7,  
15 for the blood test container according to the invention as  
recited in claim 4, the annular member is mounted between  
the outer face of the tubular member and the inner face of  
the tubular container with the aid of paraffin. When heated  
after centrifugation, the paraffin is caused to melt. It  
20 then becomes difficult for the annular member to restrict  
the movement of the serum or plasma. As a result, the serum  
or plasma, while pushing up the annular member, reaches the  
test reagent for contact therewith.

For the blood test container according to the invention  
25 as recited in claim 8, the space defined between the tubular

container and the second tubular container, inclusive of the region where the blood test reagent is secured, is sealed by the sealing member comprised of thixotropic material having a viscosity of 5,000 - 500,000 centipoise at 25 °C. The  
5 blood sample is first introduced into the second tubular and then centrifuged. During the centrifugation, the thixotropic sealing member is forced to move down toward the bottom of the tubular container, thereby opening the space. When the blood test container is subsequently turned upside  
10 down, the separated serum or plasma is allowed to enter the space to successfully contact the blood test reagent.

In accordance with the invention as recited in any one of claims 3 - 8, the provision of the contact control structure assures that the blood introduced is initially  
15 prevented from contacting the test reagent and the serum or plasma separated by the subsequent centrifugation is allowed to contact the test reagent. This leads to the practice of blood testing with increased precision.

In accordance with the invention as recited in claim 9,  
20 the aforementioned contact control structure includes the flexible inner resin tube accommodated in the tubular container. The inner tube has a peripheral surface portion brought into close contact with an inner face of the tubular container. One end portion of the inner tube has an outer  
25 diameter made smaller than an inner diameter of the tubular

container so that its peripheral surface is spaced from the inner face of the tubular container. Accordingly, prior to being centrifuged, the blood is prevented from contacting the test reagent by the close contact of the outer face of the inner tube and the inner face of the tubular container. When centrifuged, the communicating member is forced to shift in location to act to release the close contact of the outer face of the inner tube and the inner face of the tubular container, thereby assuring the contact of the serum or plasma with the blood test reagent.

In accordance with the invention as recited in claim 10, the top and bottom ends of the aforementioned inner tube is opened and an outer diameter of the top end is made smaller than the inner diameter of the tubular container such that the blood, when introduced into the inner tube, is permitted to pass through the bottom opening of the inner tube down toward the bottom portion of the tubular container where it is stored. Accordingly, when centrifuged, the communicating is forced to shift in location to act to release the close contact of the outer face of the inner tube and the inner face of the tubular container, thereby assuring the contact of the separated serum or plasma with the blood test reagent.

In accordance with the invention as recited in claim 11, the inner tube is closed at its bottom and its outer

peripheral surface adjacent the bottom is made smaller than the inner diameter of the tubular container to thereby space it from the inner face of the tubular container. On the other hand, the upper portion of the inner tube has an outer peripheral surface brought into close contact with the inner face of the tubular container so that the blood, when introduced into the inner tube, is prevented from contacting the blood test reagent. Accordingly, when the above-described blood test container is turned upside down, the subsequent centrifuging forces the communicating member to shift in location toward the top of the tubular container, whereby the close contact of the outer face of the inner tube and the inner face of the tubular container is released to allow the separated serum or plasma to successfully contact the blood test reagent.

For the blood test container according to the invention as recited in claim 12, the second tubular container is accommodated in the tubular container and secured to the inner face of the tubular container and/or the outer face of the second tubular container. Accordingly, in an exemplary case where the stopper is used to close the top opening, when the blood test container is turned upside down, the blood sample leaves from the interior of the second tubular container to enter the space between the first and second tubular containers where it is contacted with the test

reagent.

In accordance with the invention as recited in claim 13, the contact control structure includes the second tubular container accommodated in the tubular container and having at its bottom a plurality of through-holes with diameters of 0.1 - 10  $\mu\text{m}$ . Before centrifugation, the blood introduced into the second tubular container hardly leaks therefrom toward the tubular container so that its contact with the reagent is prevented. When centrifuged, the serum or plasma is forced to pass through the plurality of through-holes of the second tubular container and enter the tubular container, while the clot is retained to stay within the second tubular container. Thus, after centrifugation, the serum or plasma is allowed to successfully contact the test reagent.

In accordance with the invention as recited in claim 14, the contact control structure includes the second tubular container provided at its bottom with a plurality of 10 - 400  $\mu\text{m}$  diameter through-holes which prevent immediate passage of the blood when introduced into the second tubular container toward the tubular container. Accordingly, the blood, prior to be centrifuged, is prevented from contacting the test reagent. The subsequent centrifuging forces the blood in the second tubular container to flow into the tubular container while separating the blood into serum or

plasma and solid matter. As a result, the serum or plasma separated by the centrifugation is allowed to contact the test reagent.

For the blood test container according to the invention as recited in claim 15 or 16, the space between the tubular container and the second tubular container, inclusive of the region where the blood test reagent is secured, is sealed by the sealing member comprised of the water-soluble material or the material having a melting point of not below 40 °C.

The blood, when introduced into the blood test container, is thus prevented from accidentally flowing into the space between the tubular container and the second tubular container. After the blood sample is introduced into the second tubular container, the blood test container is turned upside down. The blood sample is allowed to contact the test reagent if the blood test container is simply left to stand according to the invention as recited in claim 12, or if the blood test container is heated to 40 °C or higher according to the invention as recited in claim 13.

For the blood test container according to the invention as recited in claim 17, the blood sample can be brought into the aforementioned space for contact with the test reagent by introducing the blood into the second tubular container, turning the blood test container upside down, and then rotating the stopper to a position where the grooves on the

first and second stopper portions are aligned with each other.

In accordance with the invention as recited in claim 18, the opening of the second tubular container is sealed by the polymer or metal film having a thickness up to 100  $\mu\text{m}$ . By partly breaking the polymer or metal film using a needle or sharp-edged cutter, the blood can be introduced into the second tubular container without fail and prevented from entering the aforementioned space.

When the blood test container is turned upside down, the blood sample is caused to enter the space between the tubular container and the second tubular container and successfully contact the blood test reagent.

In accordance with the invention as recited in claim 19, the opening of the second tubular container is sealed by the membrane formed of material having a melting point of not below 40  $^{\circ}\text{C}$ . Such a membrane, when partly broken, provides a passage through which the blood can be introduced as by using a tubular member. This prevents the blood sample from entering the space between the tubular container and the second tubular container. Thereafter, the blood test container is turned upside down and then heated to a temperature of 40  $^{\circ}\text{C}$  or higher at which the membrane is caused to melt. As a result, the blood sample is allowed to immediately enter the space and successfully contact the

blood test reagent.

For the blood test container according to the invention as recited in claim 20, the serum or plasma separating medium is accommodated in the second tubular container. Due  
5 to the presence of the separating medium, the blood, when centrifuged, can be separated successfully into the serum or plasma which is duly brought into contact with the blood test reagent for reaction therewith.

For the blood test container according to the invention  
10 as recited in claim 21, the second tubular container is provided with the trap portion for trapping erythrocyte and adjacent the trap portion with the hemocyte separating portion having a plurality of 0.1 - 20  $\mu$ m diameter through-  
15 holes. The blood is introduced into the second tubular container and then centrifuged. During the centrifugation, the serum or plasma is forced to pass through the through-  
20 holes and leave the trapping portion while the erythrocyte, because of its high specific gravity, is retained within the trapping portion. As a result, the serum or plasma is  
caused to leave the trapping portion and enter the space, between the second tubular container and tubular container, where it successfully contacts the blood test reagent.

For the blood test container according to the invention as recited in claim 22, the second tubular container is  
25 provided at its bottom portion with a plurality of through-

holes. Further, the layer comprised of 0.1 - 200  $\mu$ m hydrophilic fine particles is placed to overlies the bottom portion. When a blood sample is introduced into the second tubular container and subsequently centrifuged, the  
5 separated serum or plasma is caused to flow into the space between the second tubular container and the tubular container. On the other hand, the hemocyte is retained within the second tubular container to overlies the hydrophilic fine particle layer. As a result, the serum or  
10 plasma alone can be brought into contact with the blood test reagent.

In the case where the centrifugation is not performed, the blood is vacuum collected by reducing the interior pressure of the blood test container. This pressure  
15 reduction creates a suction force which acts to filter the serum or plasma through the hydrophilic fine particle layer. As a result, the serum or plasma alone can be brought into contact with the blood test reagent, as similar to the case as described above.

20 The second tubular container for use in the invention as recited in claim 22 can be easily fabricated by securing the bottom member having a plurality of through-holes to the tubular member as recited in claim 23.

In accordance with the invention as recited in claim  
25 24, for the blood test container according to the invention

as recited in claim 12, the second tubular container is at its bottom apertured to provide a hole and the water-soluble cover member is secured to the bottom of the second tubular container for closing the hole. The blood, when introduced  
5 into the second tubular container, is initially prevented from contacting the blood test reagent due to the presence of the water-soluble cover member which closes the hole provided in the bottom of second tubular container.

With the lapse of time, or after centrifugation, the  
10 water-soluble cover member is induced to dissolve into the water content of the blood, serum or plasma. As a result, the blood, serum or plasma is allowed to come into contact with the blood test reagent.

In accordance with the invention as recited in claim  
15 25, the hole provided in the bottom of second tubular container is closed by the cover member formed of a metal or magnet. The blood, when introduced into the second tubular container, is thus prevented from contacting the blood test reagent. The bottom hole of the second tubular container  
20 can be opened when the cover member is caused to shift in location by using an external metal or magnet. This permits the blood introduced into the second tubular container or the serum or plasma separated by subsequent centrifugation to pass through the bottom hole and enter the space between  
25 the second tubular container and the tubular container. As

a result, the blood, serum or plasma is allowed to come into contact with the blood test reagent.

In accordance with the invention as recited in claim 26, a portion of the blood test container is exposed and the remaining portion is covered with the protective film. This arrangement is effective in preventing undesired swelling of the blood test reagent.

In the blood test container according to the invention as recited in claim 27, the blood introduced into the tubular container or the serum or plasma separated by the subsequent optional centrifuging can be brought into contact with a part of the blood test reagent by the downward shift of the sliding switch. This eliminates the procedure to distribute the centrifugally separated serum or plasma into test cups, extremely reduces a risk for a tester to contact the blood, and increases the blood testing efficiency.

In accordance with the invention as recited in claim 28, the tube has a bottom end located at a position below the lowest position that the sliding switch can assume. The blood, when introduced into the tube, is thus prevented from reaching the sliding switch mounted on a side wall of the tubular container. Even in the case where the tubular container is provided with an elongated cutout or the like for slidable movement of the sliding switch therealong, the blood is prevented from leaking through the cutout to

outside, thereby assuring the increased safety.

For the blood test container according to the invention as recited in claim 29, the closed-bottom second tubular container is provided to accommodate the tubular container and the sliding switch mounted thereon and these two tubular  
5 containers are reduced in interior pressure. Accordingly, the blood can be quickly collected in the tubular container according to the vacuum blood collection procedure. After collection of the blood, or after optionally-followed  
10 centrifucation that separates the serum or plasma from the blood, the second tubular container is removed. Thereafter, the blood test procedure used for the blood test container as recited in claim 27 or 28 is followed.

Therefore, the whole procedure starting from blood  
15 collection and ending with measurement of various blood components can be safely carried out without a risk for a tester to contact the blood.

In accordance with the invention as recited in claim 30, the blood test container according to the invention as  
20 recited in any one of claims 2 - 28 is reduced in interior pressure. Accordingly, the blood can be easily introduced into the blood test container according to the vacuum blood collection procedure.

With the use of the blood test container according to  
25 the invention as recited in any one of claims 2 - 30, the

whole procedure starting from blood collection and ending with measurement of various blood components can thus be easily and precisely carried out without a risk for a tester to directly contact the blood.

5           When the blood test method according to the invention as recited in claim 31 is followed, the whole procedure starting from blood collection and ending with measurement of various blood components can be easily and precisely carried out without a risk for a tester to directly contact  
10 the blood.

          When the blood test method according to the invention as recited in claim 32 is followed, the whole procedure starting from blood collection and ending with measurement of various blood components can be easily and precisely  
15 carried out without a risk for a tester to directly contact the blood.

## C L A I M S

1. (Deleted)

2. (Amended) A blood test container characterized as  
5 including a closed-bottom tubular container and a blood test  
reagent secured within the tubular container, and  
further including a contact control structure effective  
to normally prevent the contact of blood introduced in said  
tubular container with said test reagent and, when  
10 centrifuged, allow a component of the blood to contact the  
test reagent.

3. The blood test container as recited in claim 2,  
wherein said contact control structure includes an inner  
container portion extending along an inner face toward a  
15 bottom of said tubular container and apertured to have a  
hole at its bottom, and a solid member accommodated in said  
inner container portion for closing the hole and configured  
to fall through the hole when centrifuged, and

wherein said blood test reagent is provided onto either  
20 the inner face of the tubular container or on an outer face  
of the inner container portion.

4. The blood test container as recited in claim 2,  
wherein said contact control structure includes an open-  
ended tubular member accommodated in the tubular container,  
25 and an annular member radially extending between the outer

face of the tubular member and the inner face of the tubular container to contact therewith and positioned to initially locate below said test reagent, and

5 wherein the blood test reagent is provided on at least one of the inner face of the tubular container and the outer face of the tubular member.

10 5. The blood test container as recited in claim 2, wherein said contact control structure includes an open-ended tubular member accommodated in the tubular container and having a bottom end brought into contact with an interior bottom face of the tubular container, and a pressing means for pressing the tubular member against the interior bottom face of the tubular container so that the blood introduced into the tubular member is prevented from  
15 leaking therefrom and, when centrifuged, a component of the blood is allowed to leak therefrom, and

wherein said blood test reagent is provided on at least one of the inner face of the tubular container and the outer face of the tubular member.

20 6. The blood test container as recited in claim 2, wherein said contact control structure includes an open-ended tubular member secured onto the inner face of the tubular container, and a solid member secured adjacent a bottom end of the tubular member for closing a bottom  
25 opening of the tubular member and designed to fall down

therethrough when centrifuged, and wherein said test reagent is secured to locate at a position above said solid member.

7. The blood test container as recited in claim 4, wherein inner and outer peripheral surfaces of said annular member are secured to the outer face of the tubular member and the inner face of the tubular container, respectively, with the aid of paraffin of the formula  $C_nH_{2n+2}$  (where n is 18 - 22).

8. The blood test container as recited in claim 2, characterized that said contact control structure includes an open-ended tubular member having a smaller diameter than the tubular container for arrangement within the tubular container,

that said blood test reagent is secured onto at least one of the inner face of the tubular container and the outer face of the tubular member, and

that a space defined between the tubular container and the tubular member, inclusive of a region where the blood test reagent is secured, is sealed by a sealing member comprised of thixotropic material having a viscosity of 5,000 - 500,000 centipoise at 25 °C.

9. (Amended) The blood test container characterized that the blood test container includes a closed-bottom tubular container and a blood test reagent secured within the tubular container,

that said contact control structure includes:

a flexible inner resin tube accommodated in the tubular

container and having a peripheral surface portion brought into close contact with an inner face of the tubular container and an end portion dimensioned to have an outer diameter smaller than an inner diameter of the tubular container so that its peripheral surface is spaced from the inner face of the tubular container to provide a space therebetween, and

a communicating member disposed within said space so as to be moveable; and

that said blood test reagent is located within the space and secured onto either the inner face of the tubular container or the outer face of the inner tube.

10. The blood test container as recited in claim 9, wherein said inner tube is opened at its top and bottom ends and an outer diameter of said top end is made smaller than the inner diameter of the tubular container.

11. The blood test container as recited in claim 9, wherein said inner tube has a closed bottom and an outer diameter of its portion adjacent the bottom is made smaller than the inner diameter of the tubular container.

12. (Amended) The blood test container characterized that the blood test container includes a closed-bottom tubular container and a blood test reagent secured within the tubular container, and

further includes a bottom-closed second tubular container having a smaller diameter than said tubular container and accommodated within the tubular container, and

that said blood test reagent is provided on at least one of the inner face of the tubular container and the outer face of the second tubular container.

13. The blood test container as recited in claim 12,  
5 characterized that said second tubular container is provided at its bottom with a plurality of through-holes having diameters of 0.1 - 10  $\mu\text{m}$ .

14. The blood test container as recited in claim 12,  
characterized that said second tubular container is provided  
10 at its bottom with a plurality of through-holes having diameters of 10 - 400  $\mu\text{m}$ , and a porous region including said plurality of through-holes is located at a position below said test reagent.

15. The blood test container as recited in claim 12,  
15 characterized that a space defined between the tubular container and the second tubular container, inclusive of a region where the blood test reagent is secured, is sealed by a sealing member comprised of water-soluble material.

16. The blood test container as recited in claim 12,  
20 characterized that a space defined between the tubular container and the second tubular container, inclusive of a region where the blood test reagent is secured, is sealed by a sealing member comprised of material having a melting point of not below 40  $^{\circ}\text{C}$ .

25 17. The blood test container as recited in claim 12,

characterized as further including a stopper having:

5 a first stopper portion extending upwardly from a distal end of the stopper and having a relatively small diameter dimensioned to be press fitted into a top opening of the second tubular container;

a second stopper portion neighboring the first stopper portion and sized to be press fitted into a top opening of the tubular container;

10 said first stopper portion having on its outer face a groove extending upwardly from its bottom end to points which are located above its out face region that is to be press fitted in the second tubular portion; and

15 said second tubular container having on its inner face a groove extending downwardly from its top end to points which are located below its inner face region that receives the first stopper portion.

20 18. The blood test container as recited in claim 12, characterized that said hole provided in the bottom of the second tubular container is sealed by a polymer or metal film having a thickness up to 100  $\mu\text{m}$ .

19. The blood test container as recited in claim 12, characterized that said hole provided in the bottom of the second tubular container is sealed by a film formed of material having a melting point of not below 40 °C.

25 20. The blood test container as recited in any one of

claims 12 - 19, characterized as further including a serum or plasma separating medium accommodated in said second tubular container.

21. The blood test container as recited in claim 12,  
5 characterized that said second tubular container has at its bottom a downwardly-projecting trap portion for trapping erythrocyte and is provided adjacent the trap portion with a hemocyte separating portion having a plurality of through-holes 0.1 - 20  $\mu\text{m}$  in diameter.

10 22. The blood test container as recited in claim 12, characterized that said second tubular container has at its bottom a plurality of through-holes and that a layer comprised of 0.1 - 200  $\mu\text{m}$  hyrophilic fine particles is disposed to overlies said through-holes.

15 23. The blood test container as recited in claim 22, characterized that said second tubular container includes a tubular member opened at its both ends and a bottom member secured onto the bottom end of the tubular member and having said plurality of through-holes.

20 24. The blood test container as recited in claim 12, characterized as further including a water-soluble cover member secured to the bottom of the second tubular container for closing said hole provided in the bottom of the second tubular container.

25 25. The blood test container as recited in claim 12,

characterized as further including a cover member formed of a metal or magnet and secured to the bottom of said second tubular container for closing said hole provided in the bottom of the second tubular container.

5           26. (Amended) The blood test container as recited in any one of claims 2 - 25, wherein a part of said blood test reagent is exposed and the remaining part thereof is covered with a protective layer so that its contact with blood or the like is prevented.

10           27. (Amended) The blood test container as recited in claim 2, characterized that the blood test container further includes a sliding switch arranged to slidably grip a side wall of the tubular container for vertical movement along the side wall, and

15           that said blood test reagent is secured to a portion of the sliding switch that locates within the tubular container.

20           28. The blood test container as recited in claim 27, further including a tube having a smaller diameter than said tubular container and accommodated in the tubular container, said tube having a bottom end located at a position below the lowest position that the sliding switch can assume.

25           29. The blood test container as recited in claim 27 or 28, characterized that the blood test container further

includes:

a closed-bottom second tubular container arranged to accommodate said tubular container carrying the sliding switch, and

5 a stopper provided to simulataneously close respective top openings of said two tubular containers; and

that the two tubular containers are both reduced in interior pressure.

30. (Amended) The blood test container as recited in  
10 any one of claims 2 - 28, wherein an interior of the blood test container is reduced in pressure.

31. (Amended) A blood test method characterized as comprising, in sequence, introducing blood into the blood test container as recited in any one of claims 2 - 30 and  
15 allowing the blood or its component to contact said blood test reagent.

32. (Amended) A blood test method characterized as comprising, in sequence, introducing blood into the blood test container as recited in any one of claims 2 - 31 and,  
20 subsequent to centrifugation thereof, allowing a component of the blood to contact said blood test reagent.

33. (Added) A blood test container characterized as including a closed-bottom tubular container and a test reagent for immunochromatography fixed within said tubular  
25 container.

34. (Added) A blood test container as recited in claim  
33, wherein a portion of said test reagent for  
immunochemistry is exposed and the remaining portion  
thereof is covered with a protective layer so that the  
5 contact of the test reagent for immunochemistry with  
blood or the like is prevented at the remaining portion.

FIG. 1

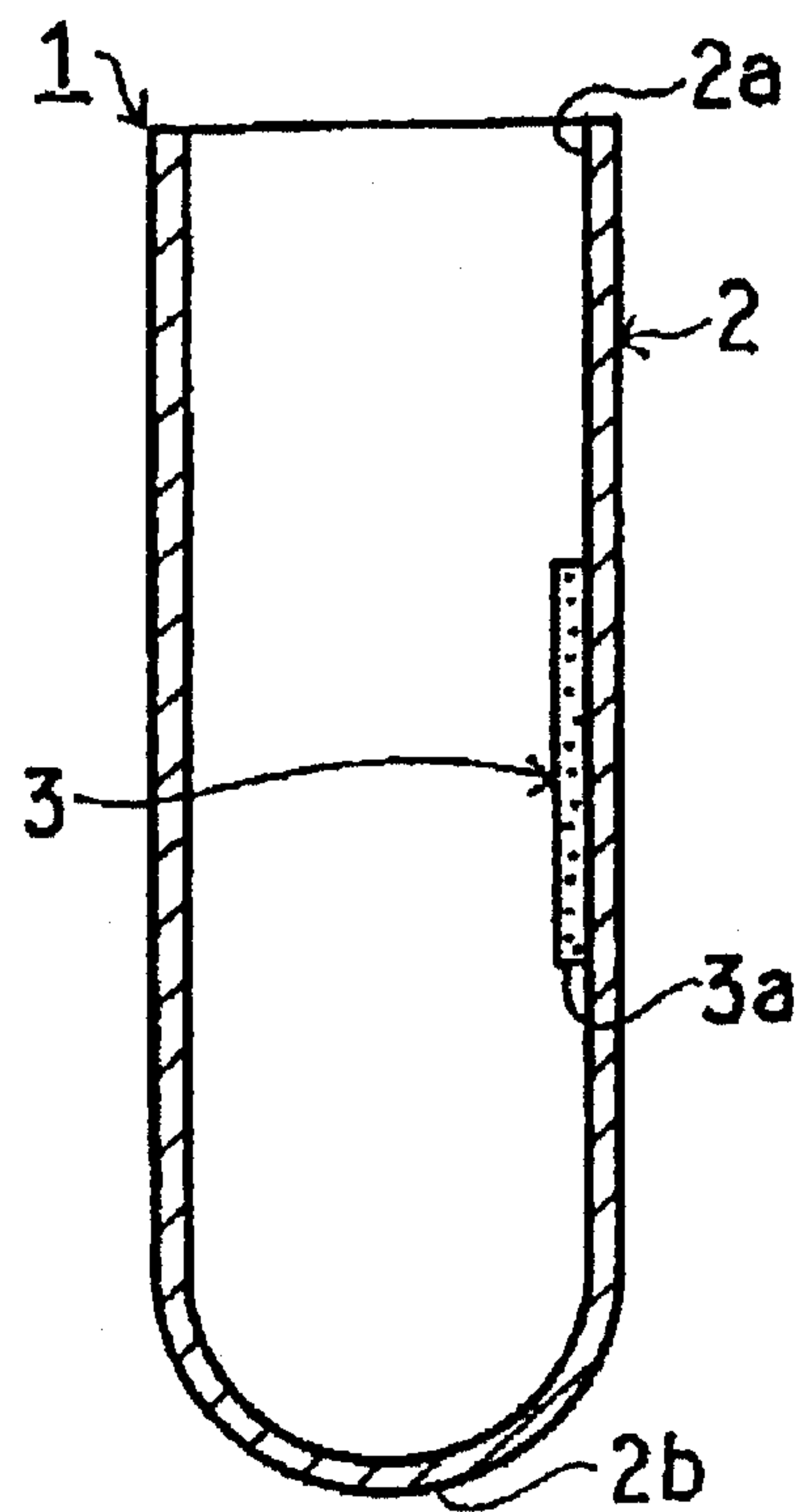


FIG. 2

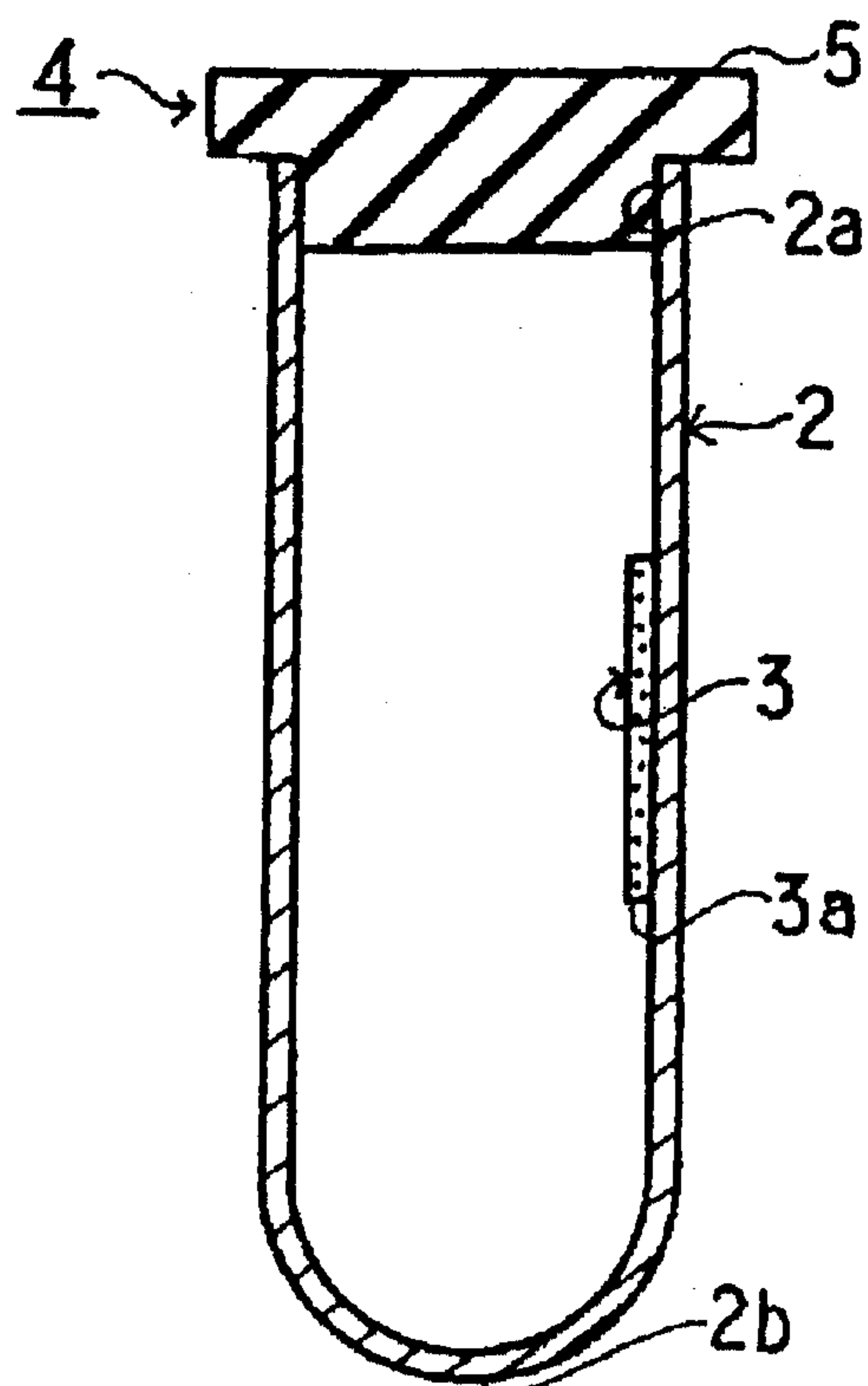


FIG. 3

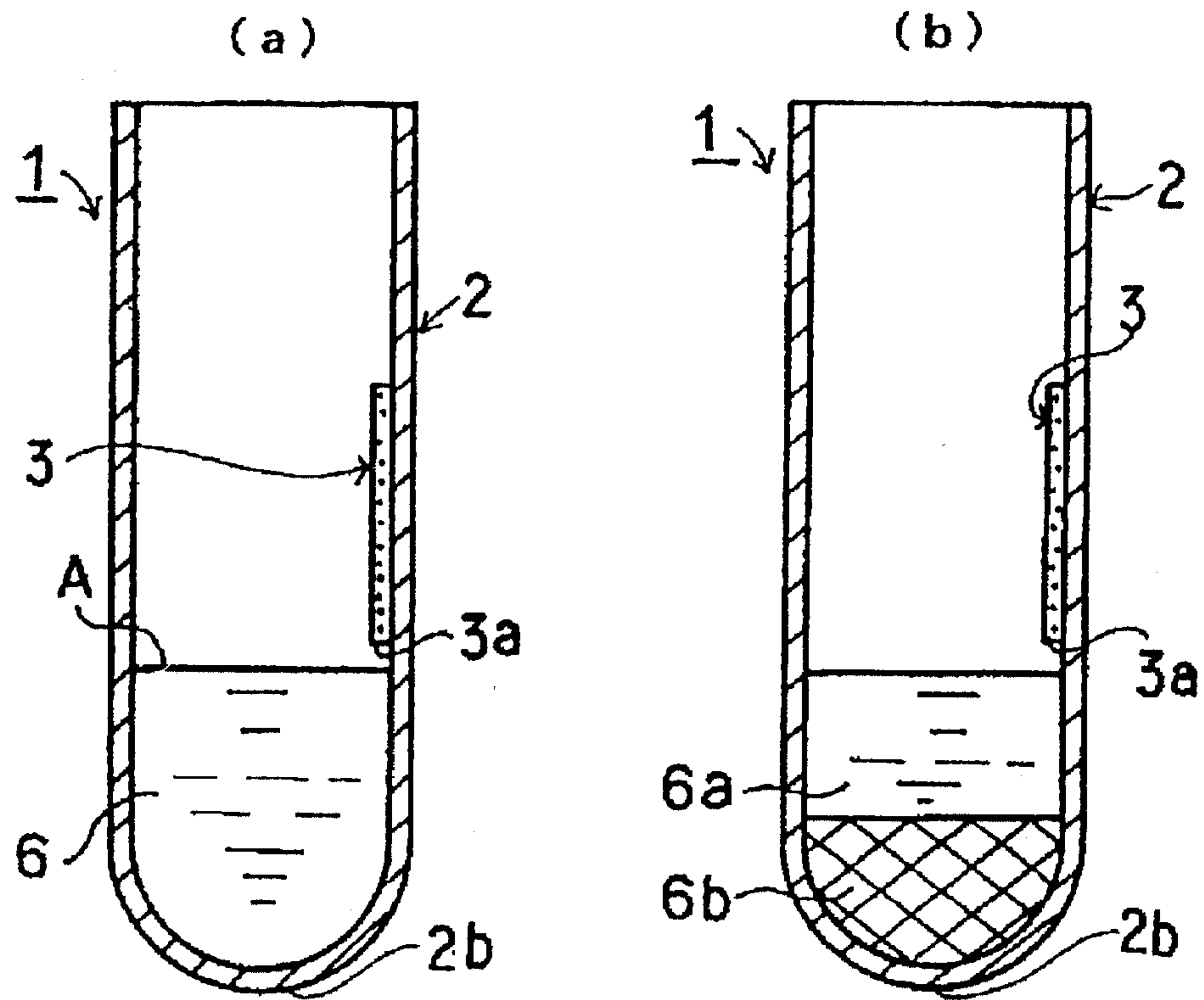


FIG. 4

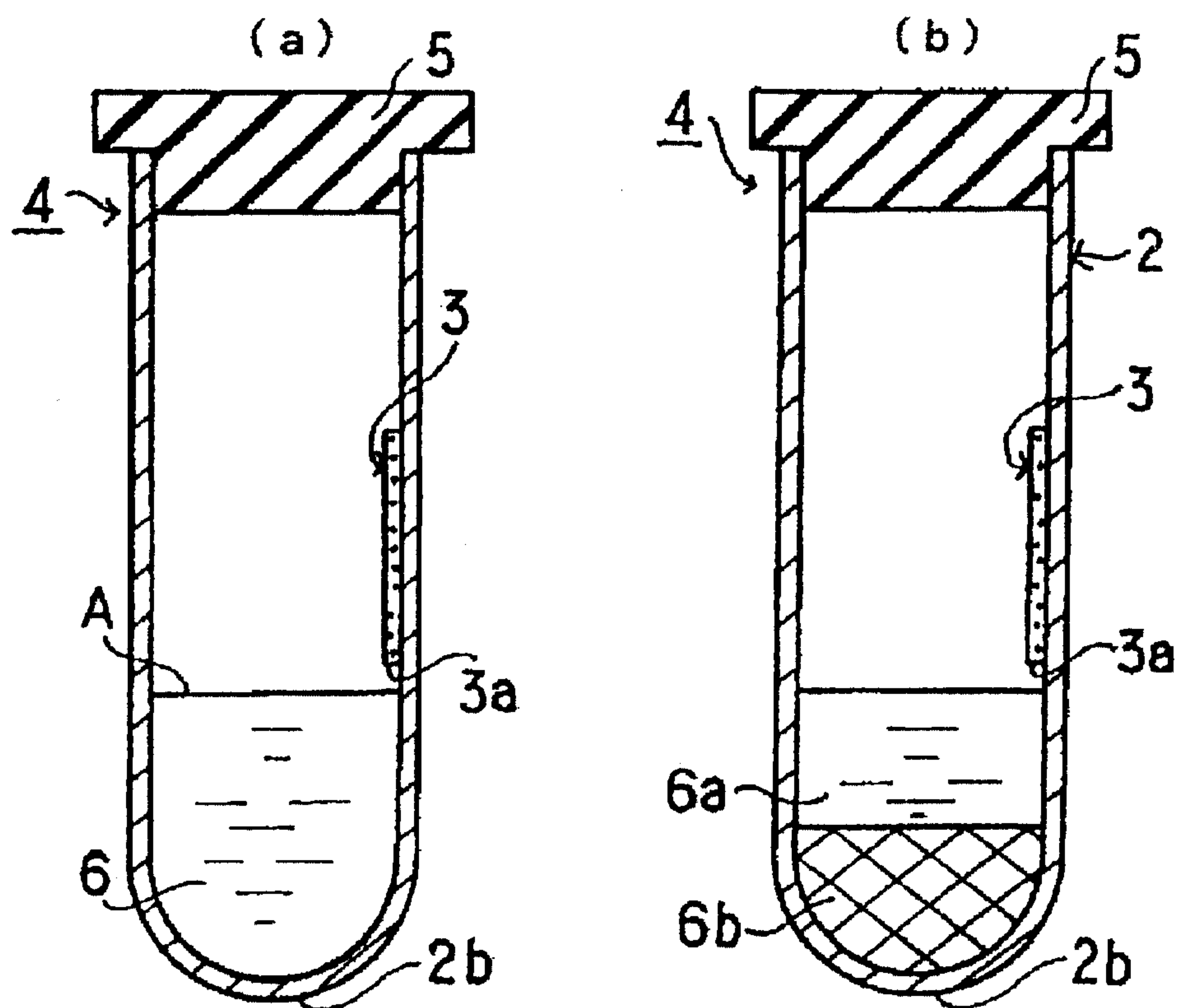


FIG. 5

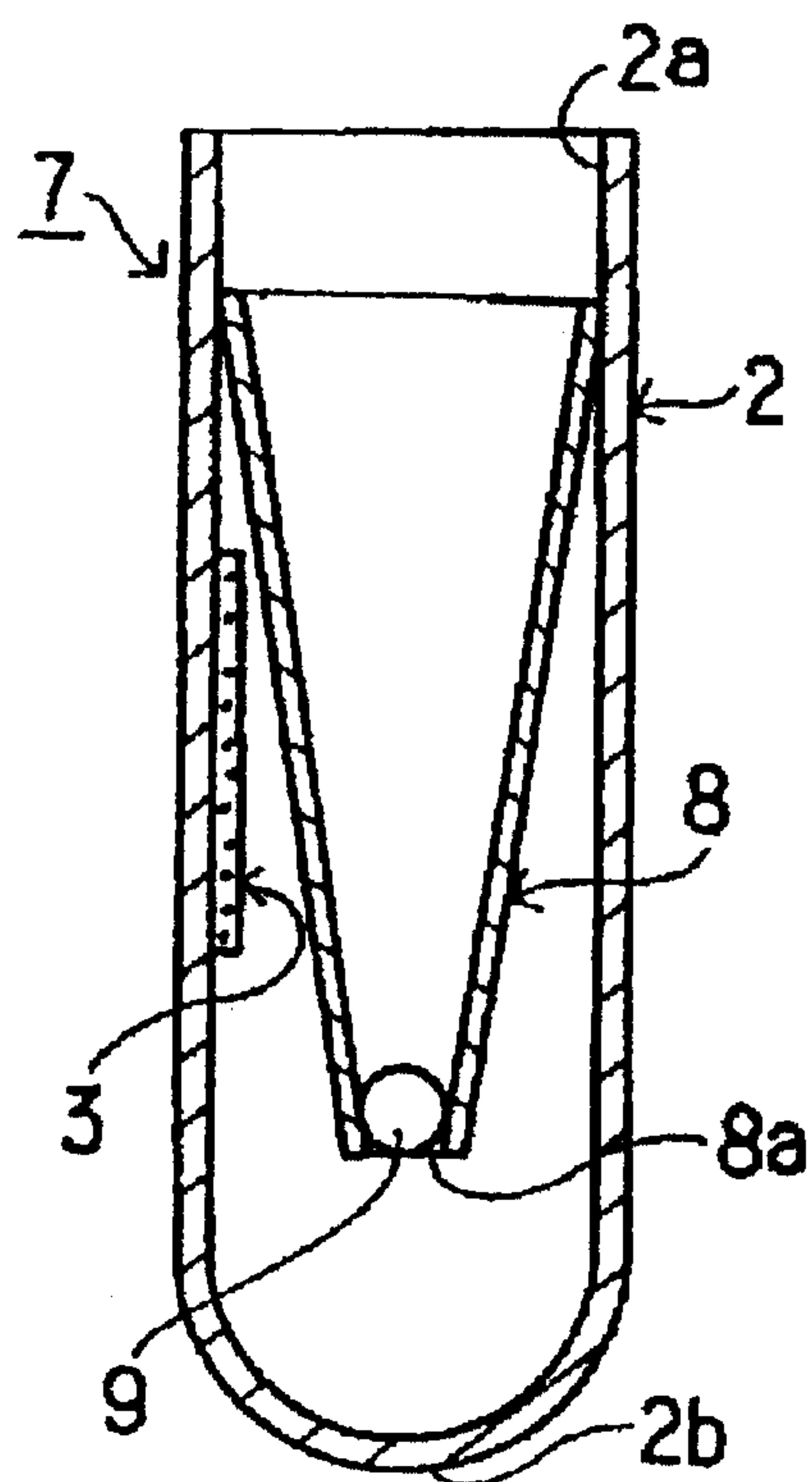


FIG. 6

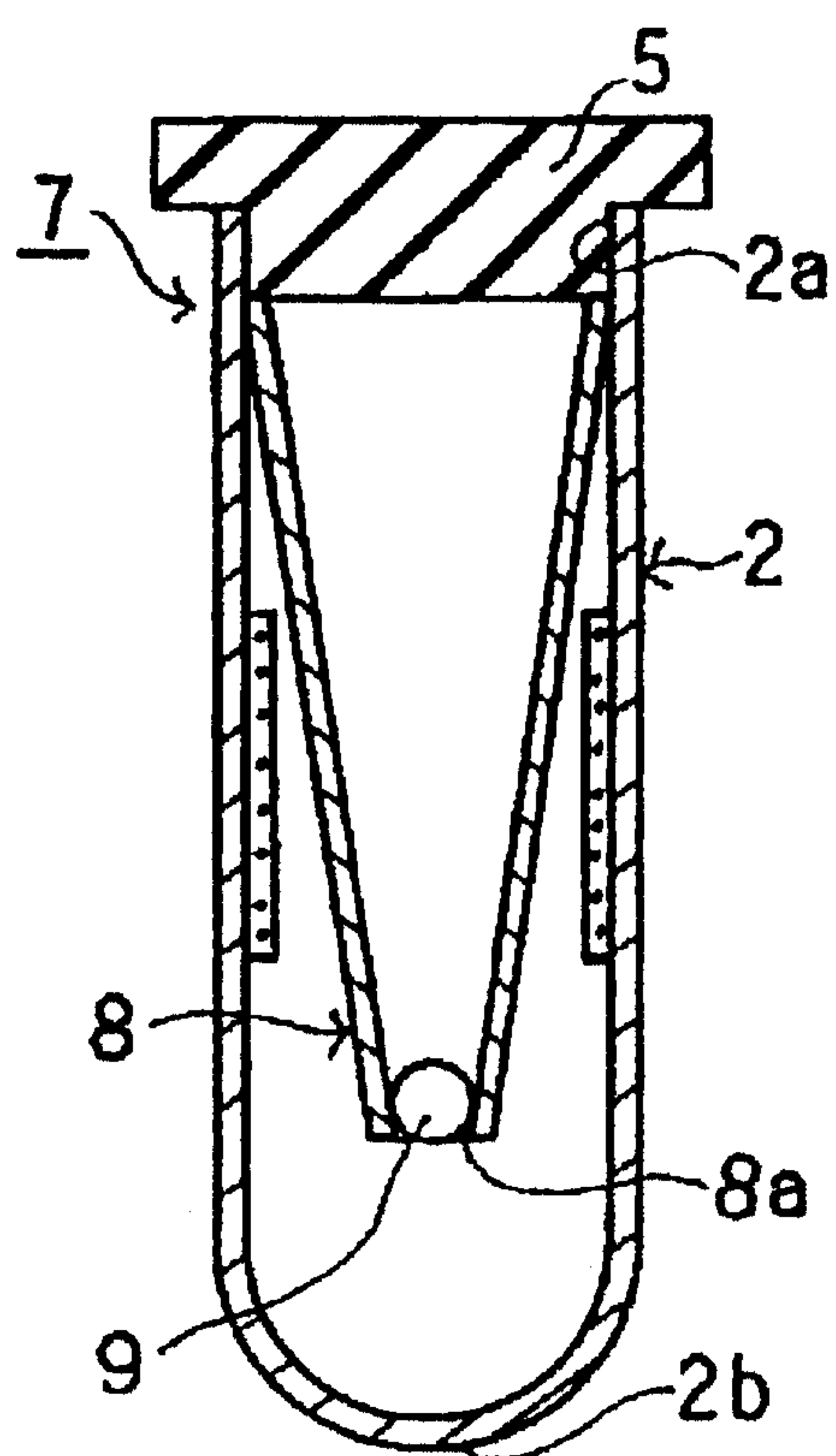


FIG. 7

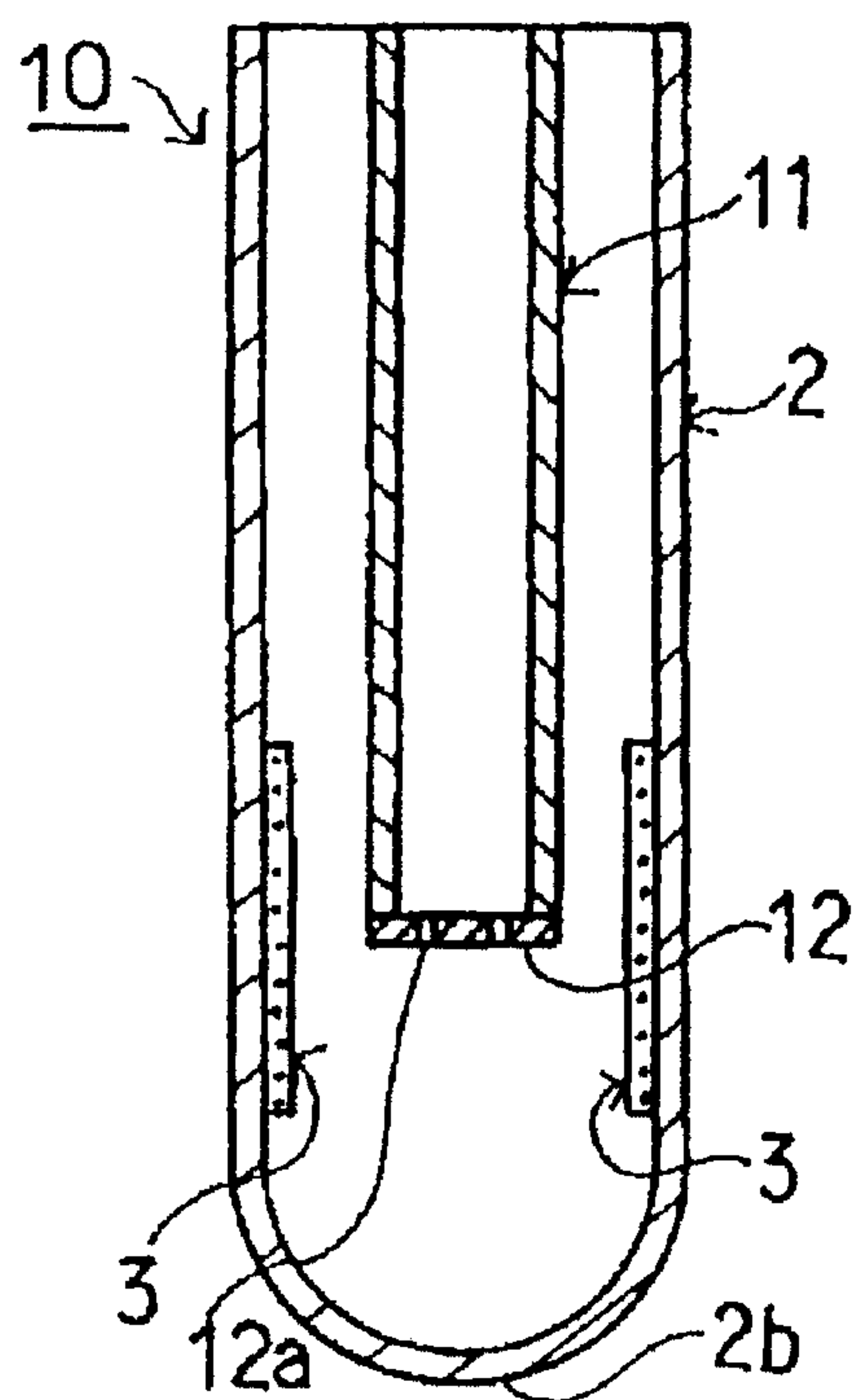


FIG. 8

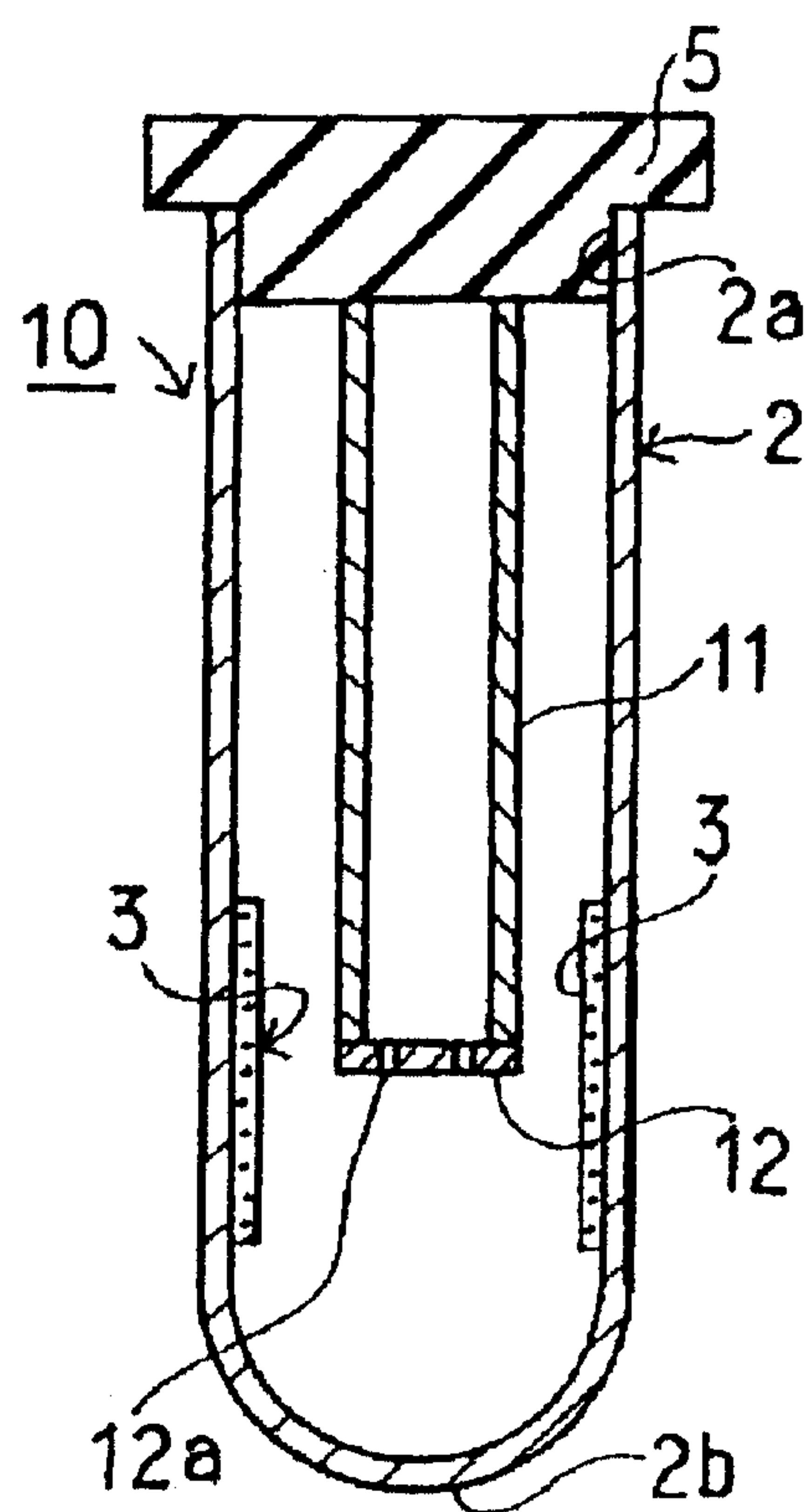


FIG. 9

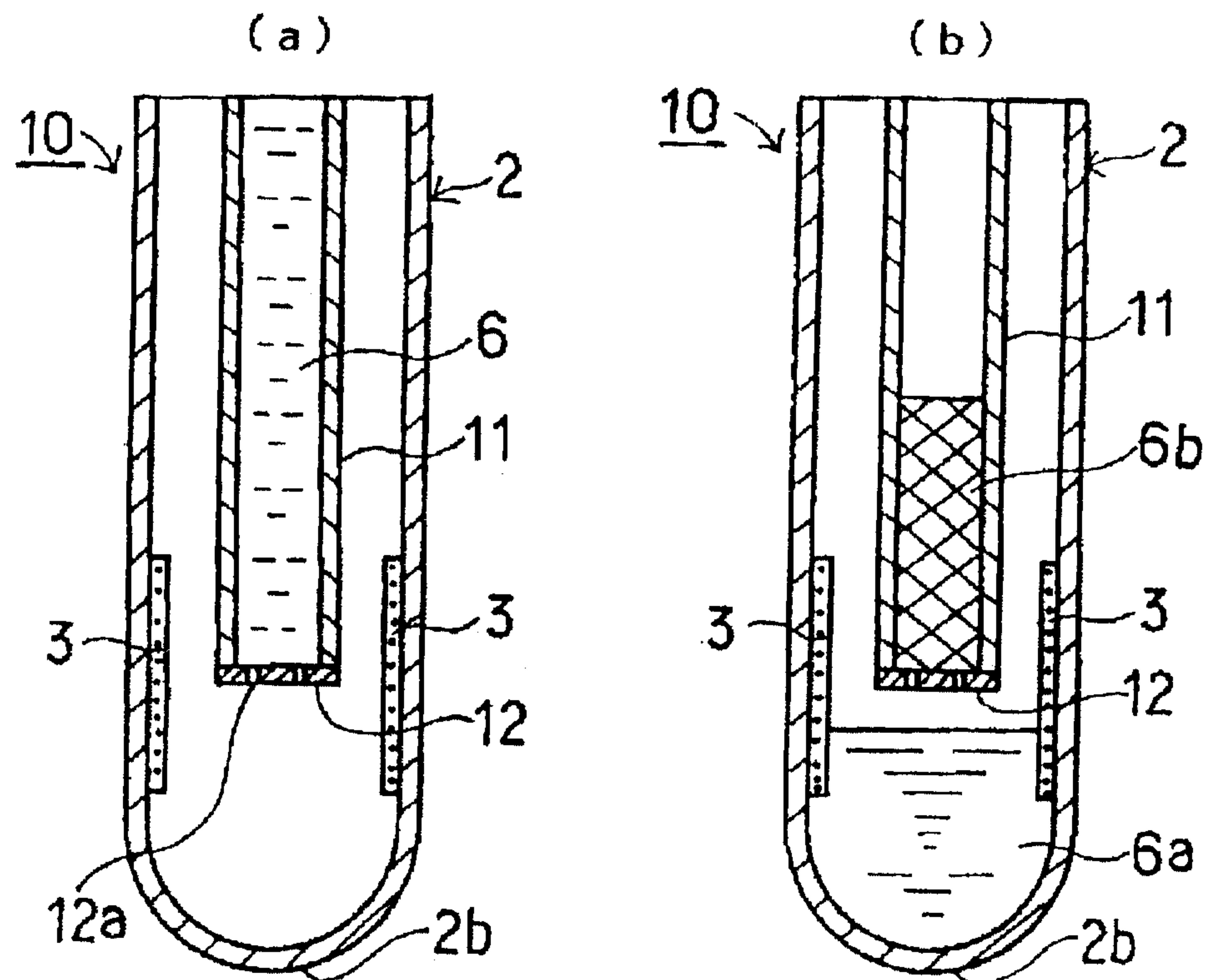


FIG. 10

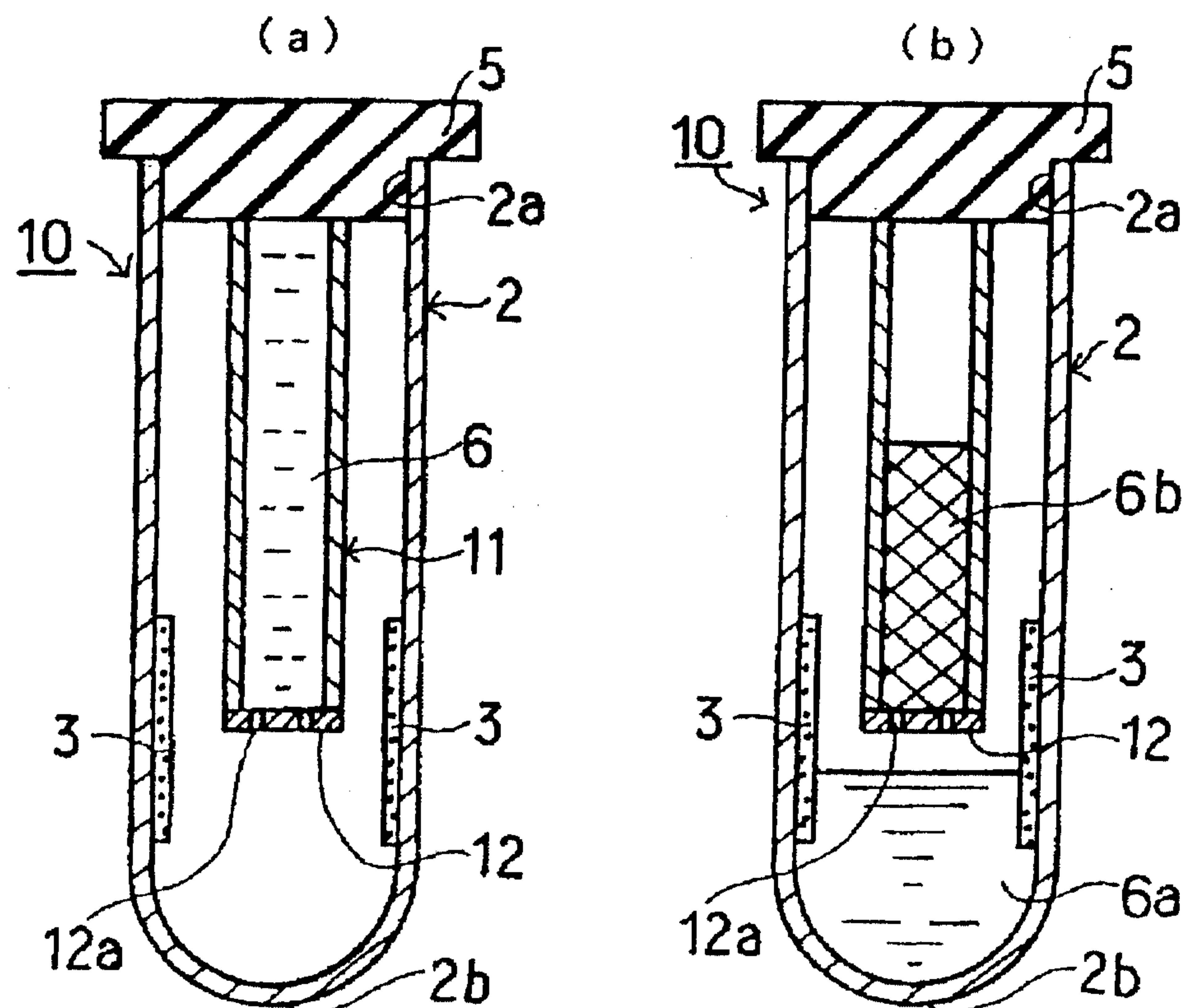


FIG. 11

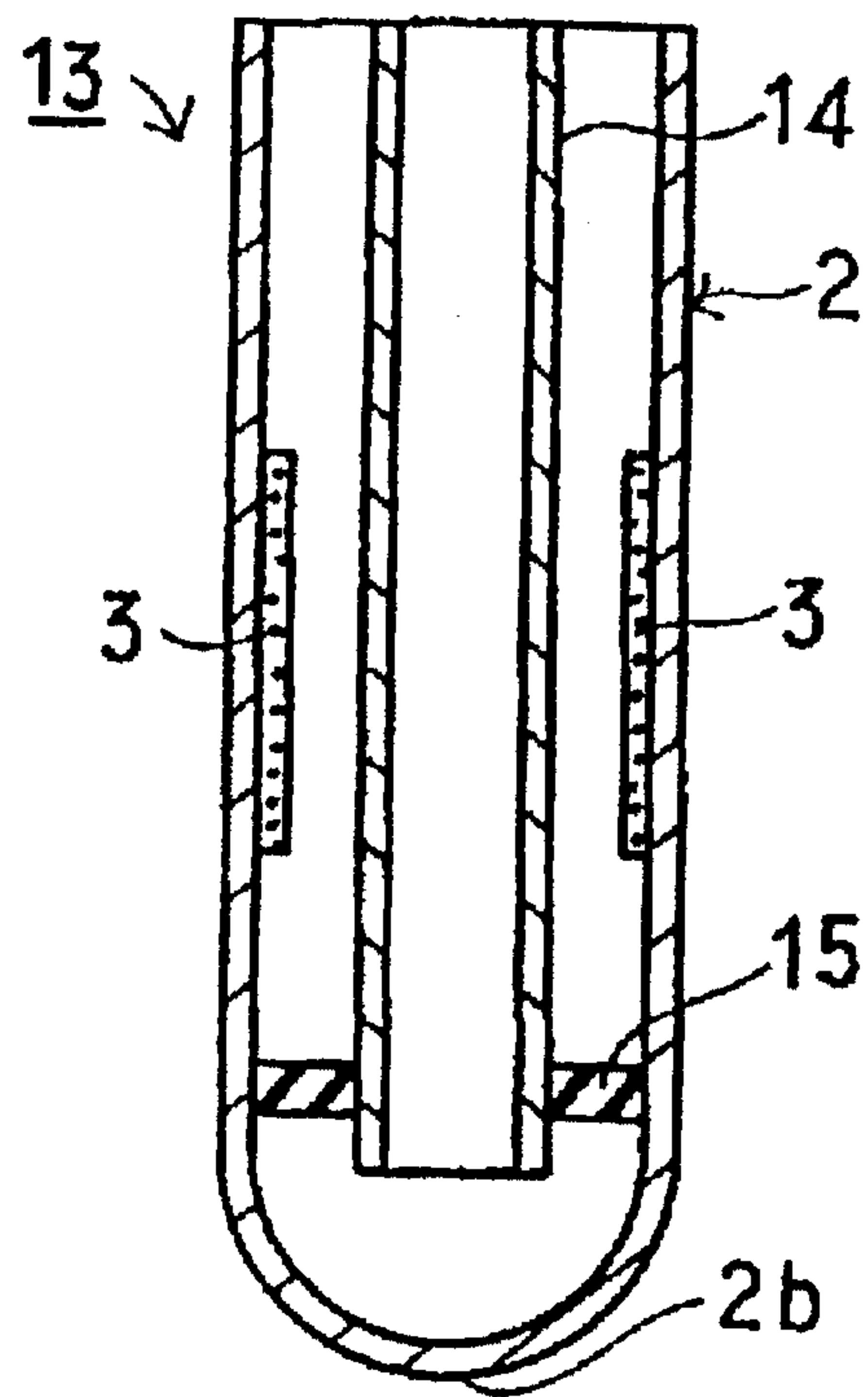


FIG. 12

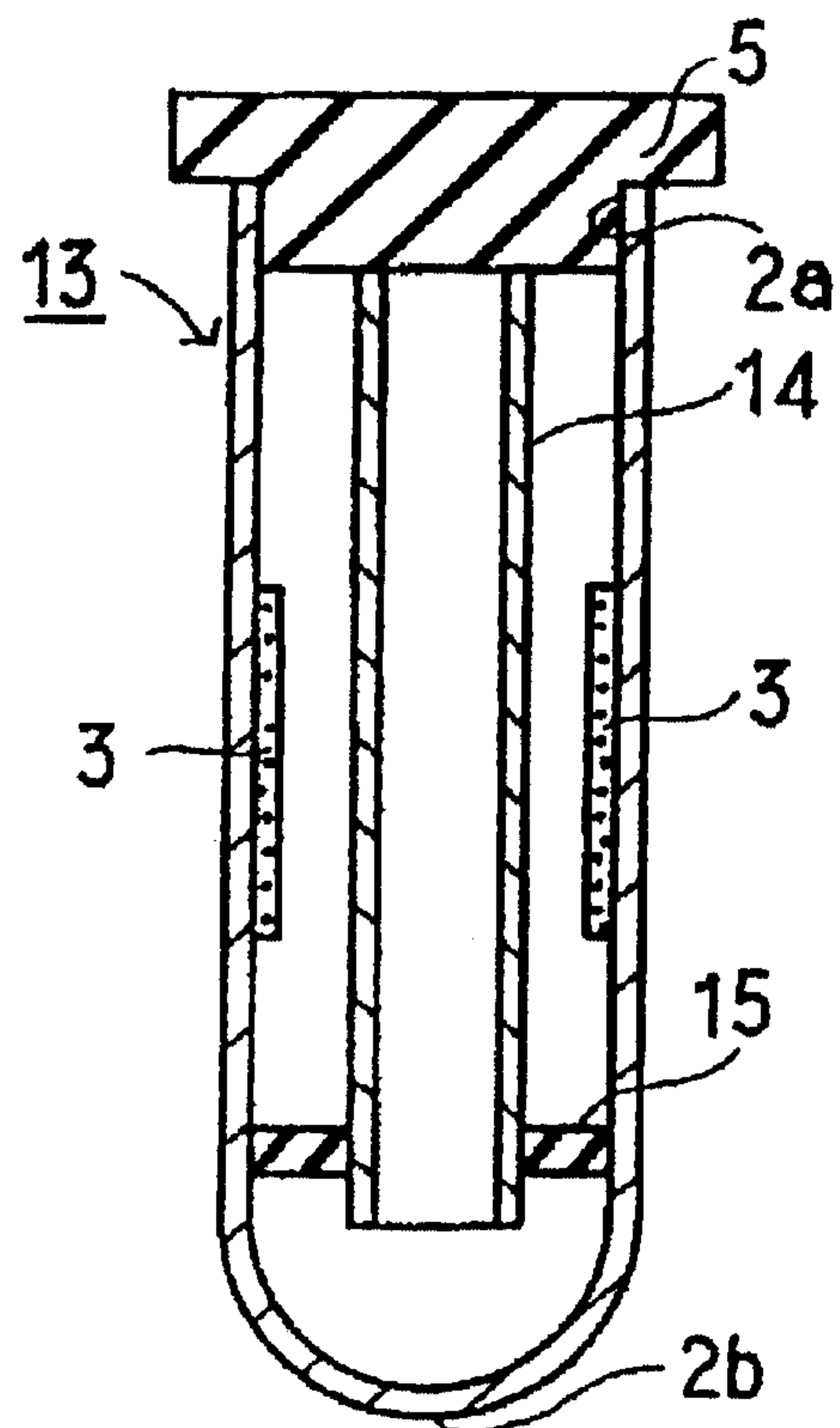


FIG. 13

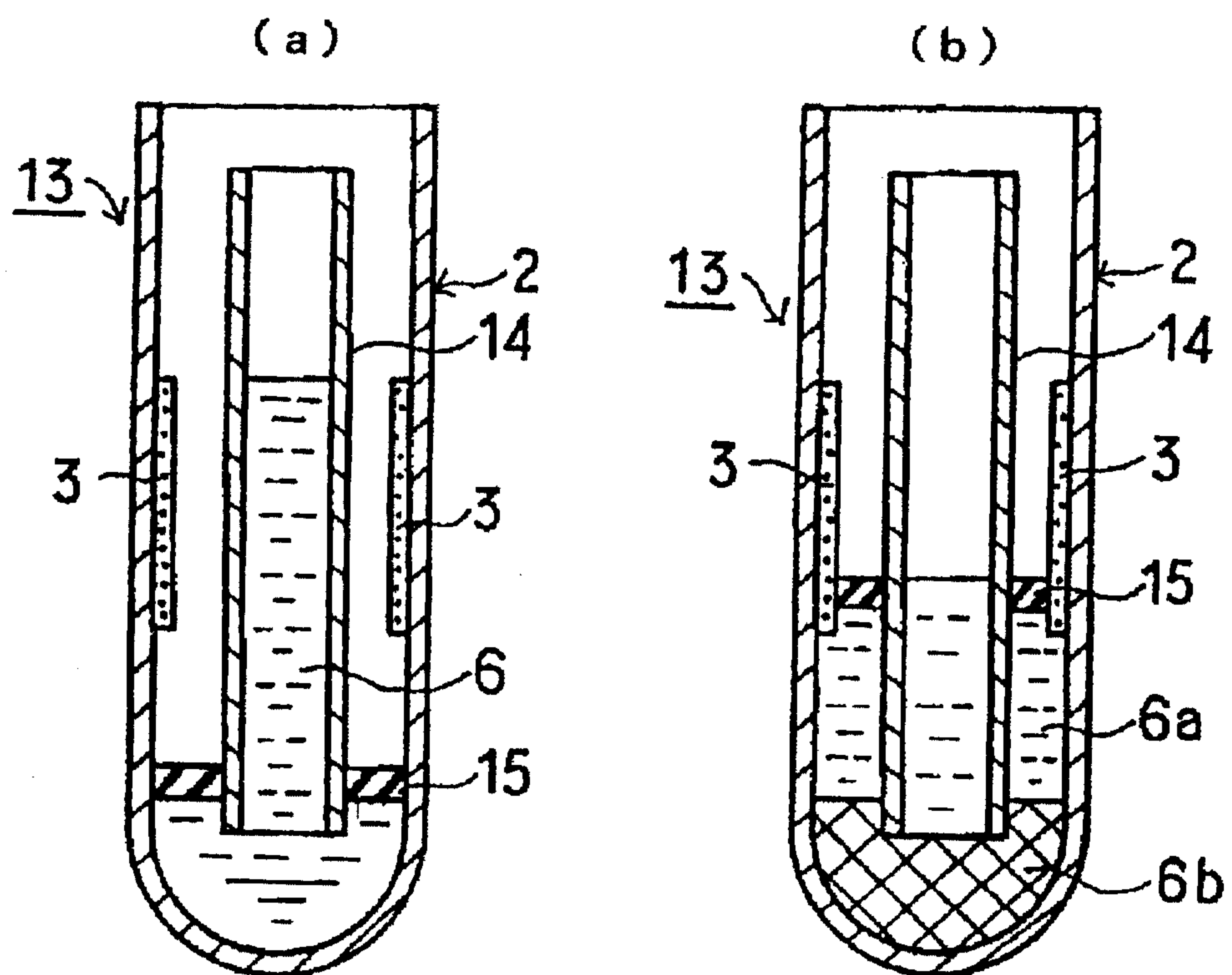


FIG. 14

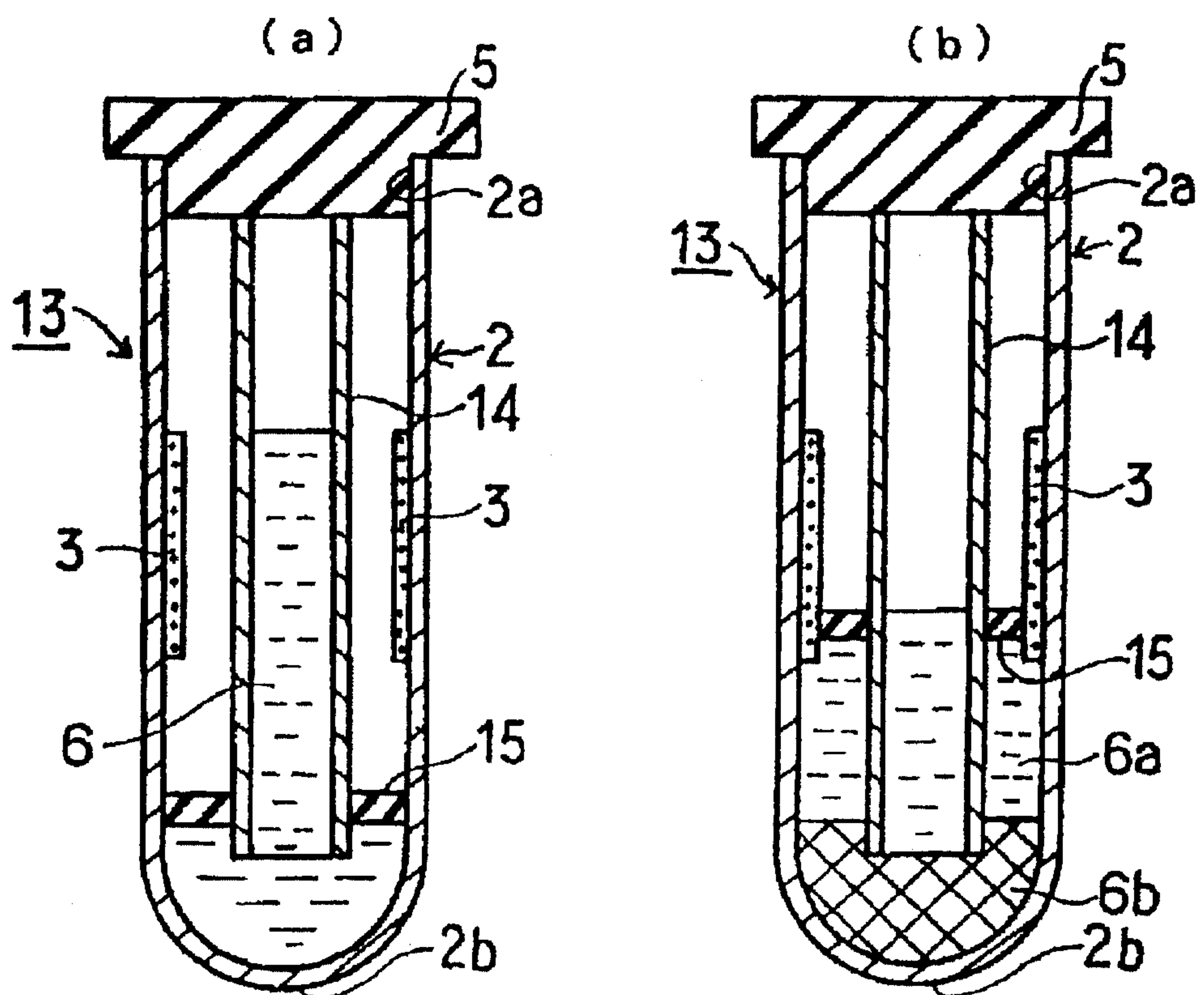


FIG. 15

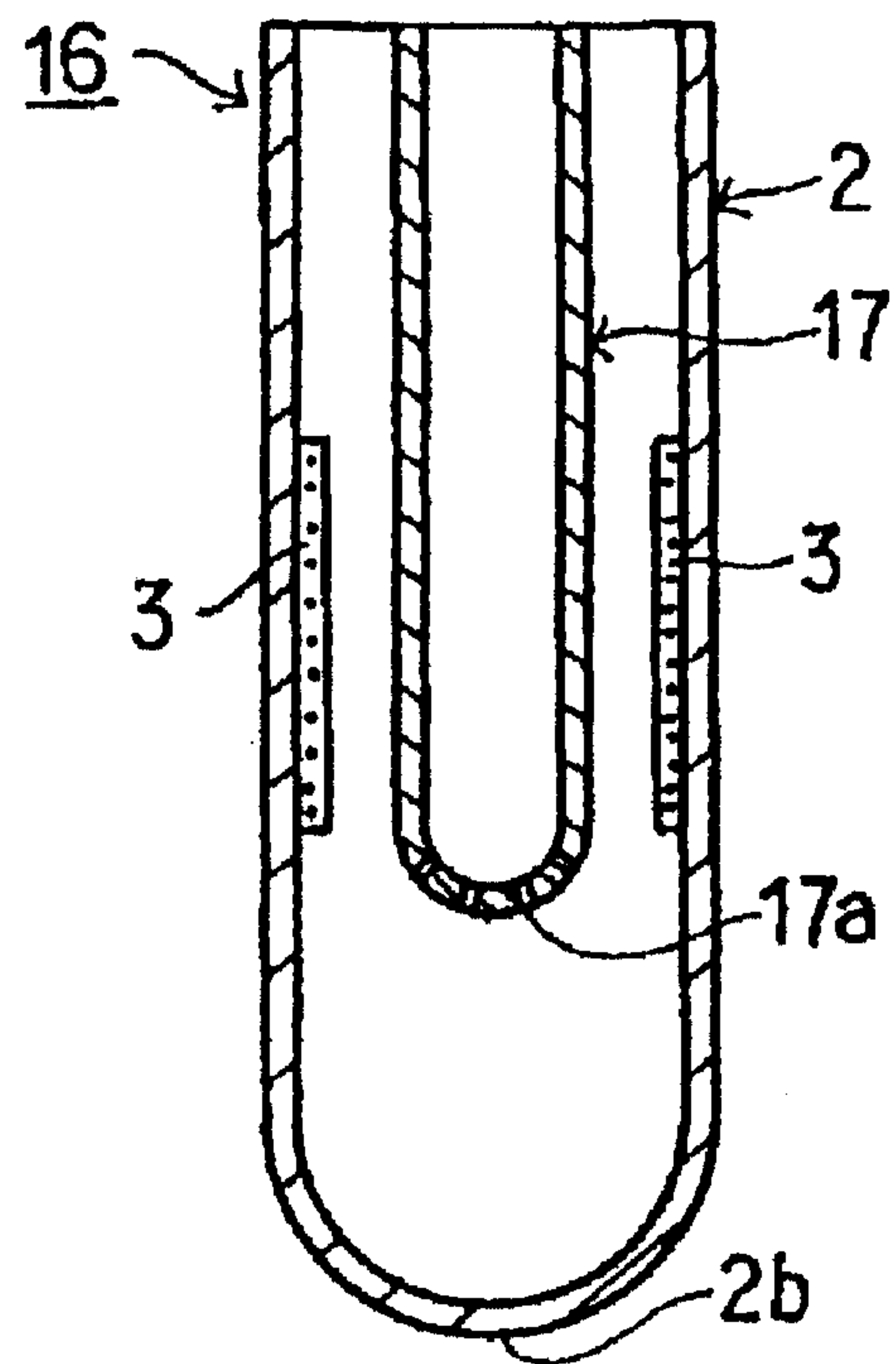


FIG. 16

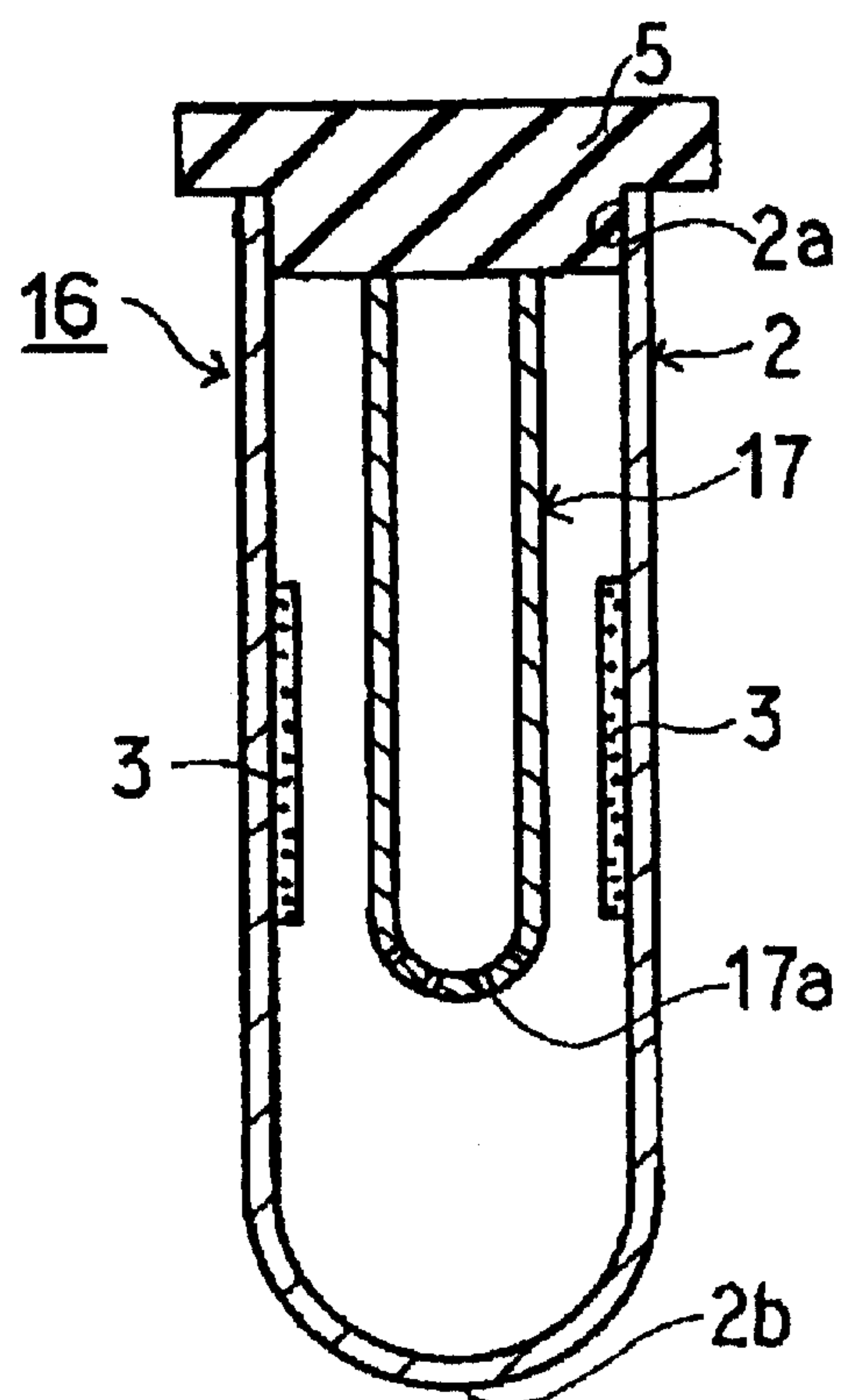


FIG. 17

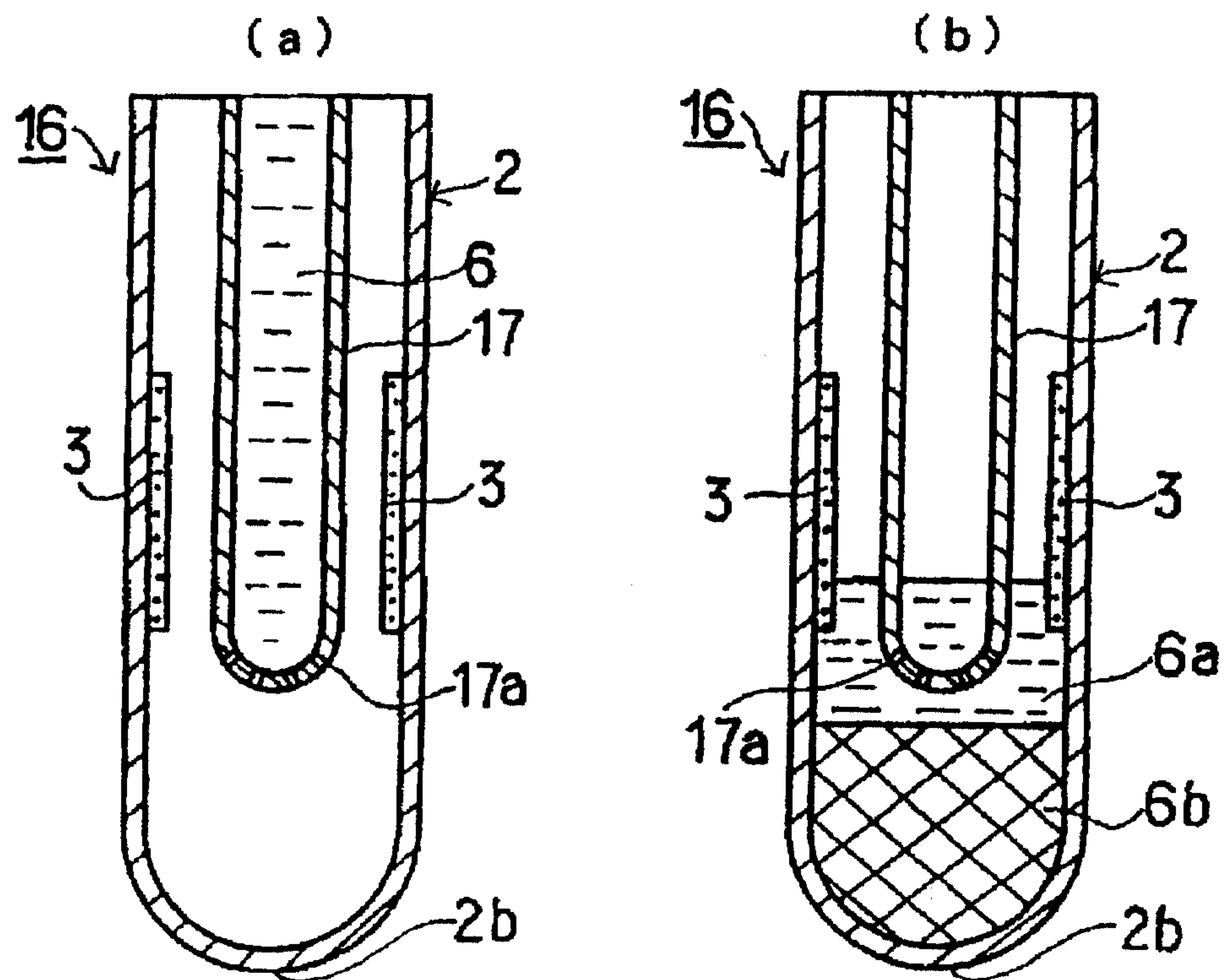


FIG. 18

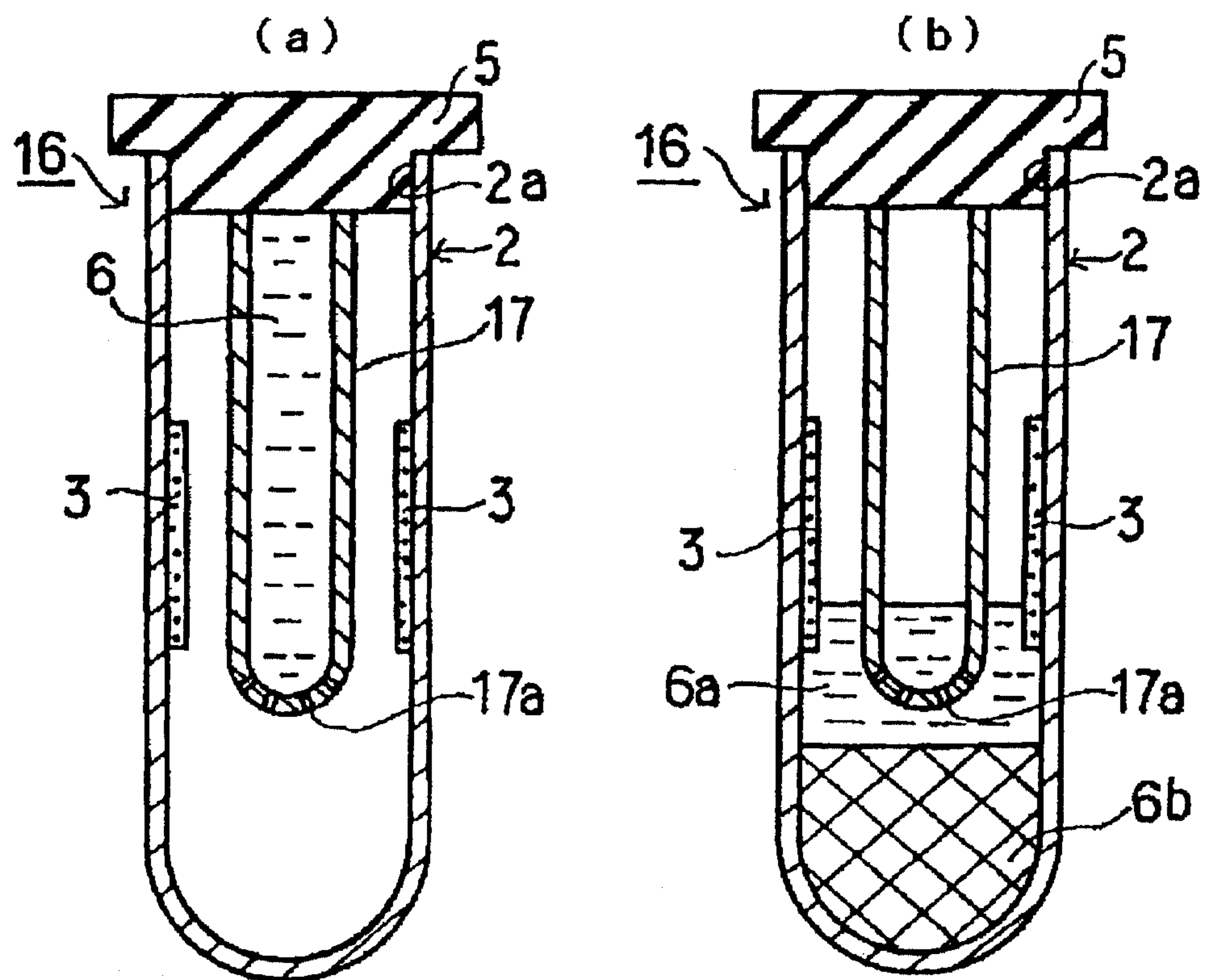


FIG. 19

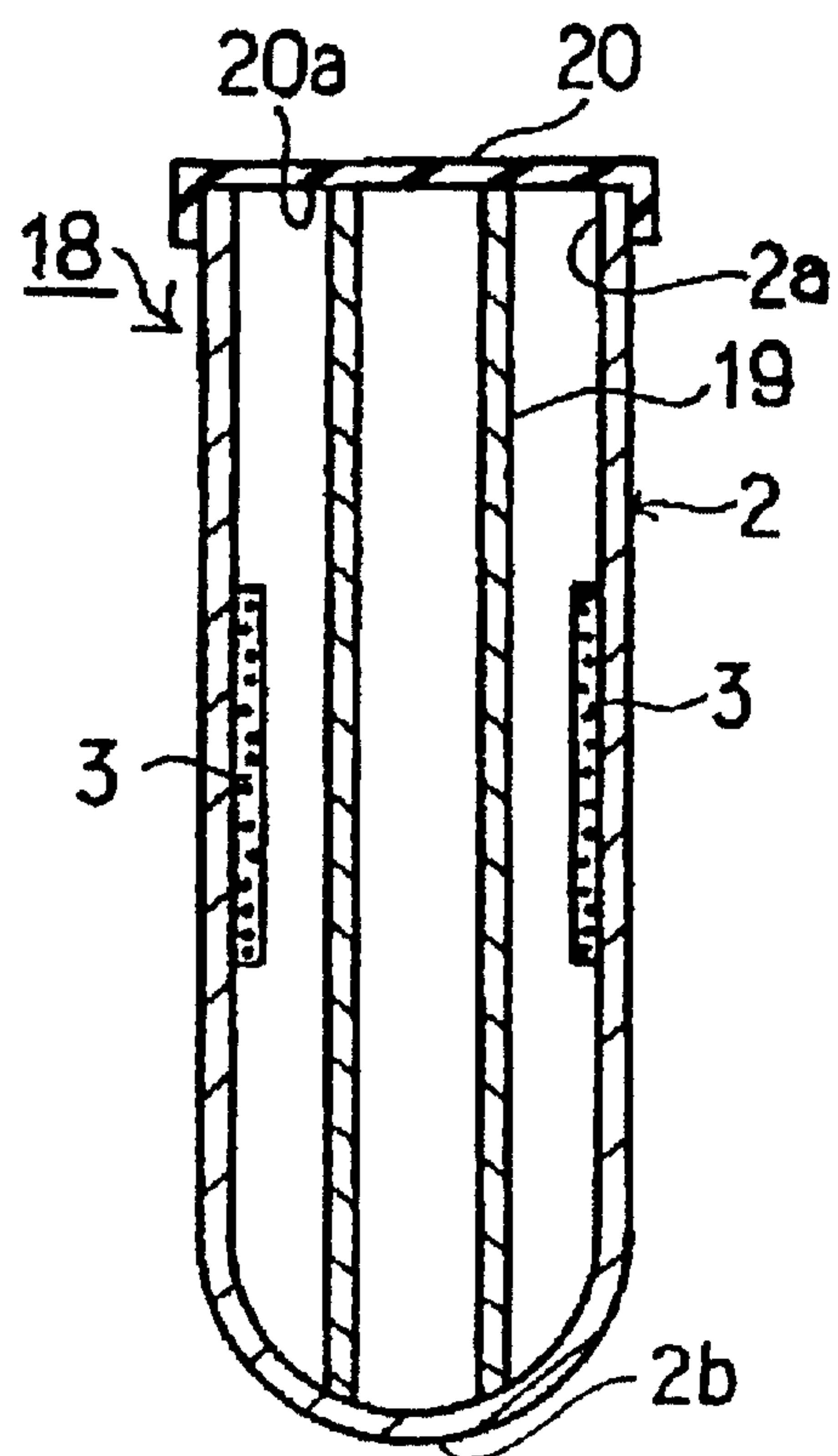


FIG. 20

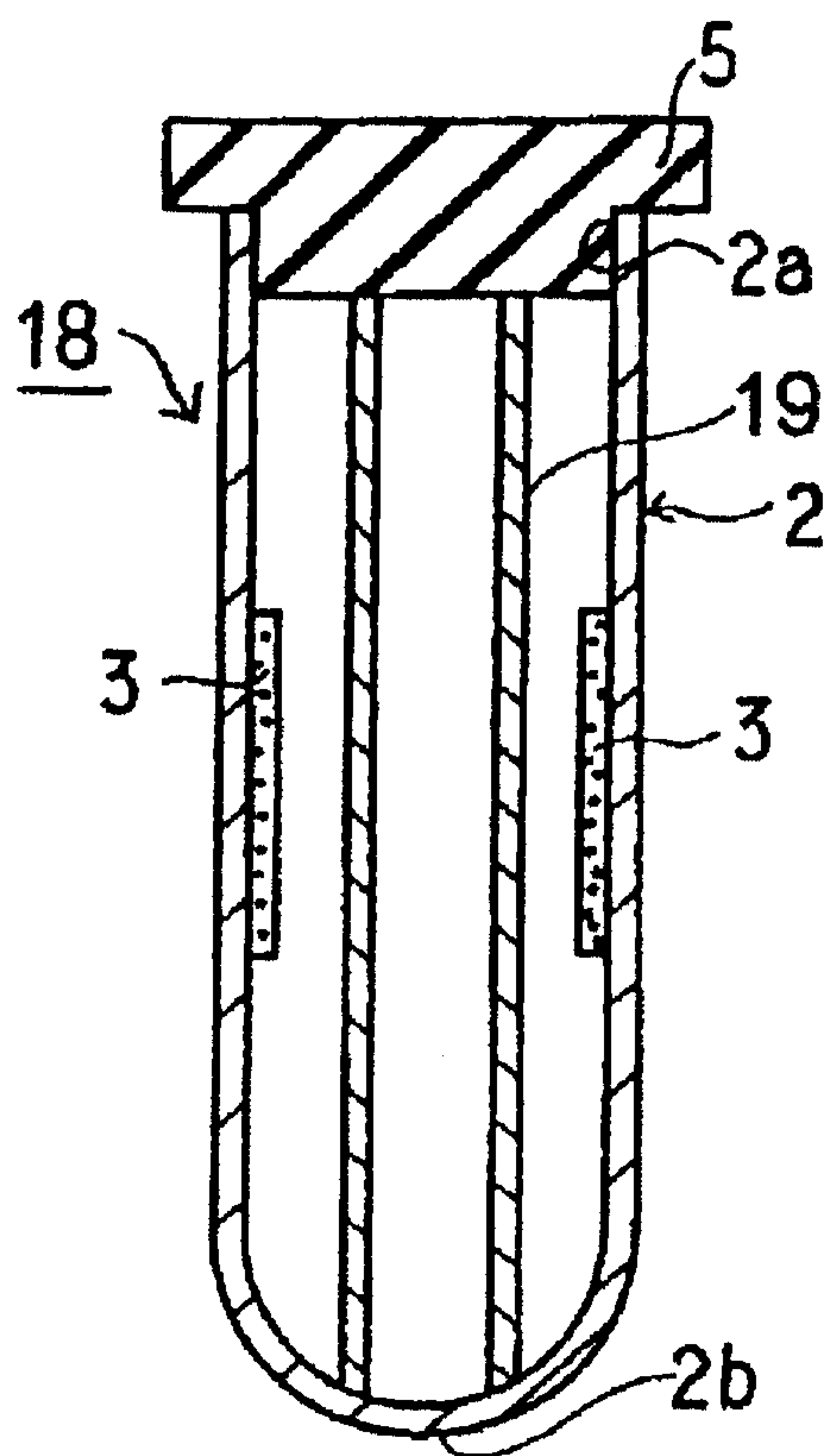


FIG. 21

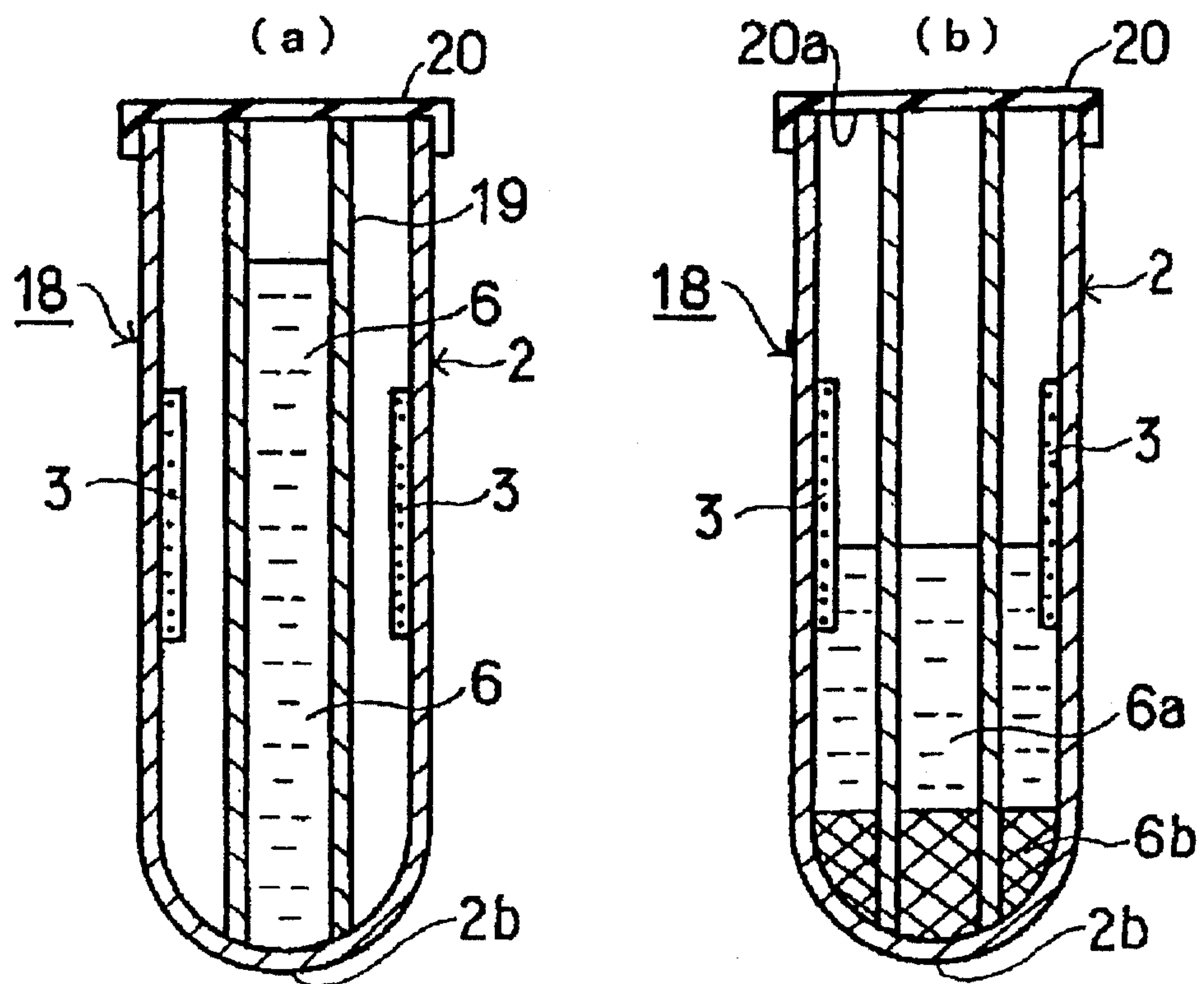


FIG. 22

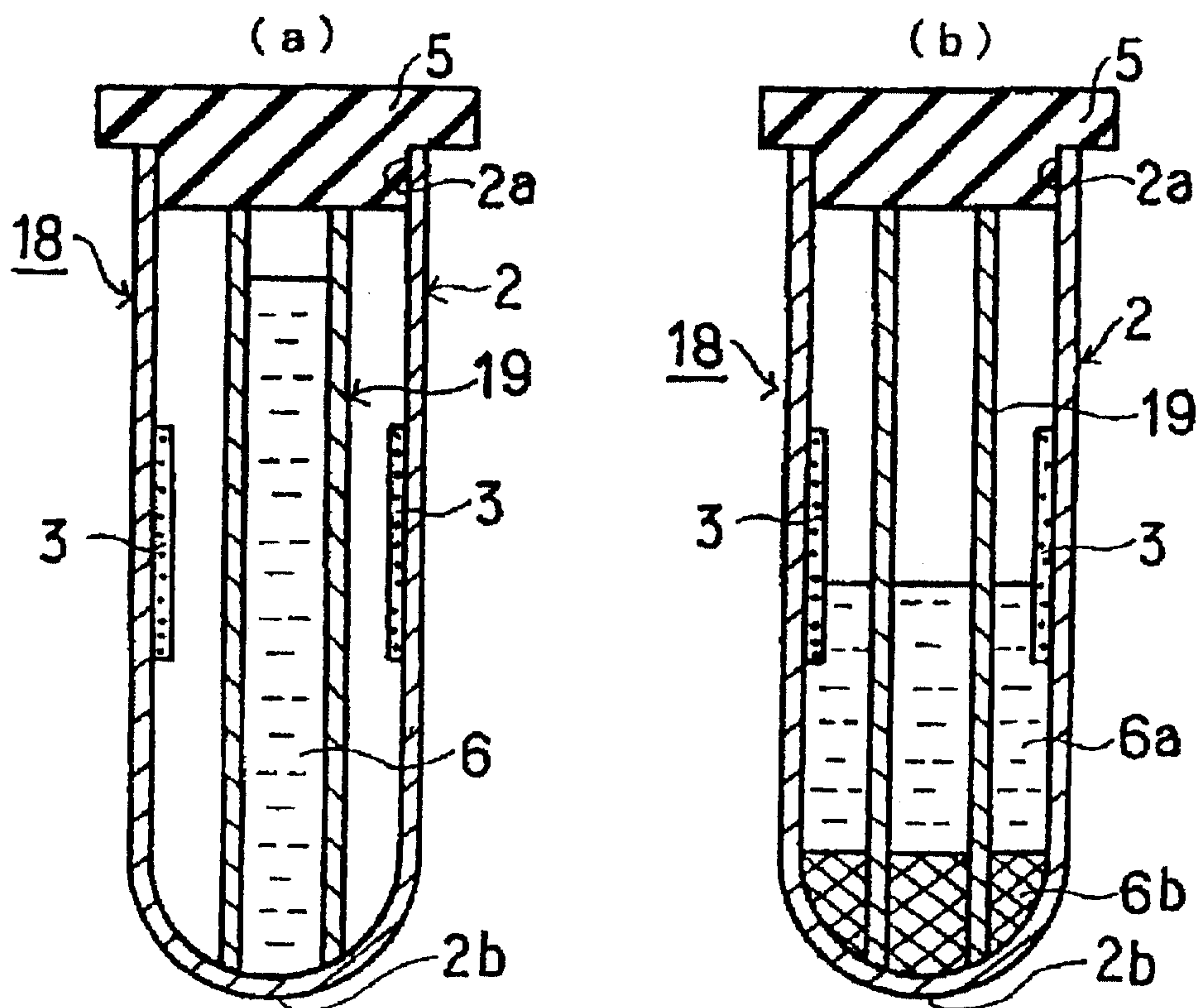


FIG. 23

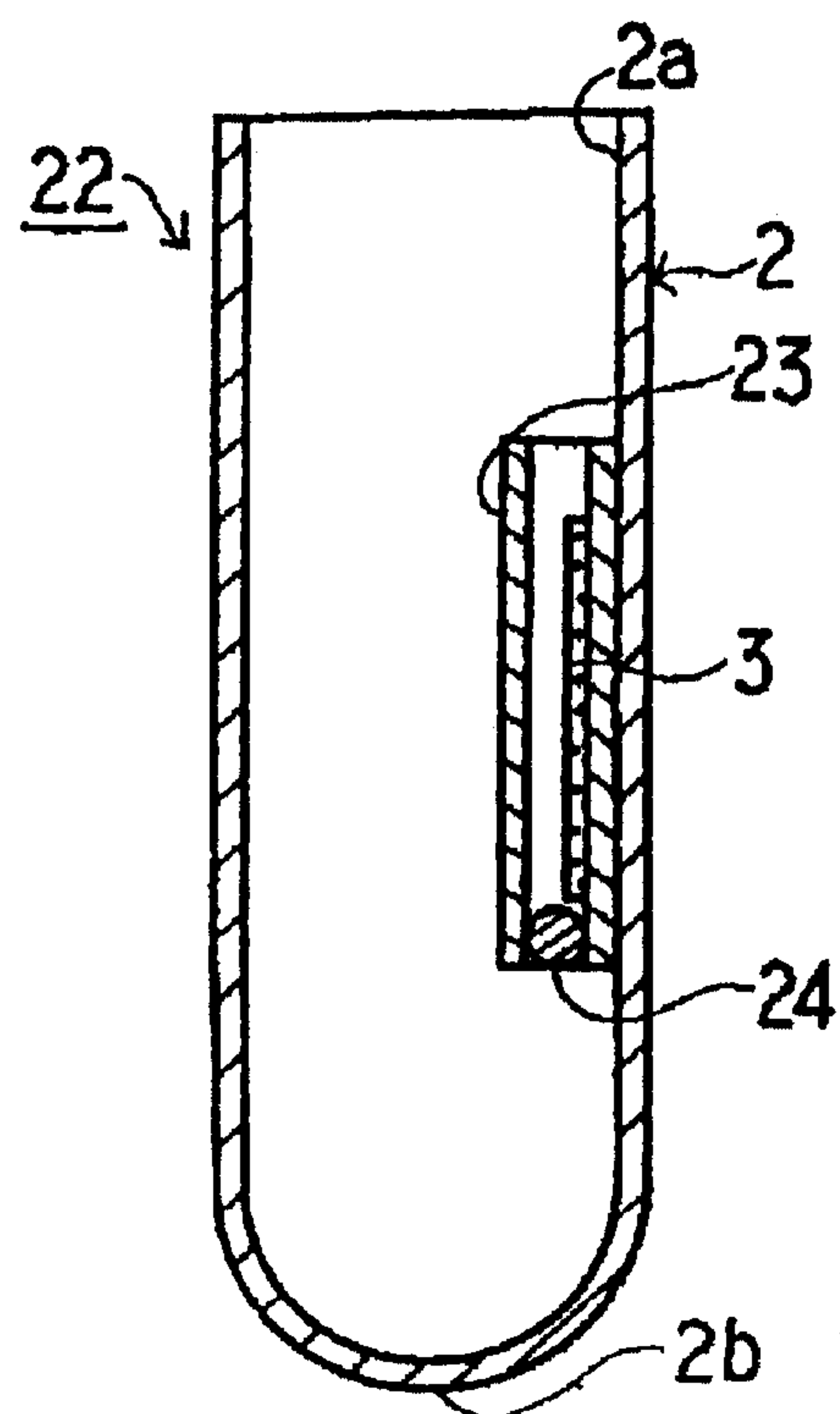


FIG. 24

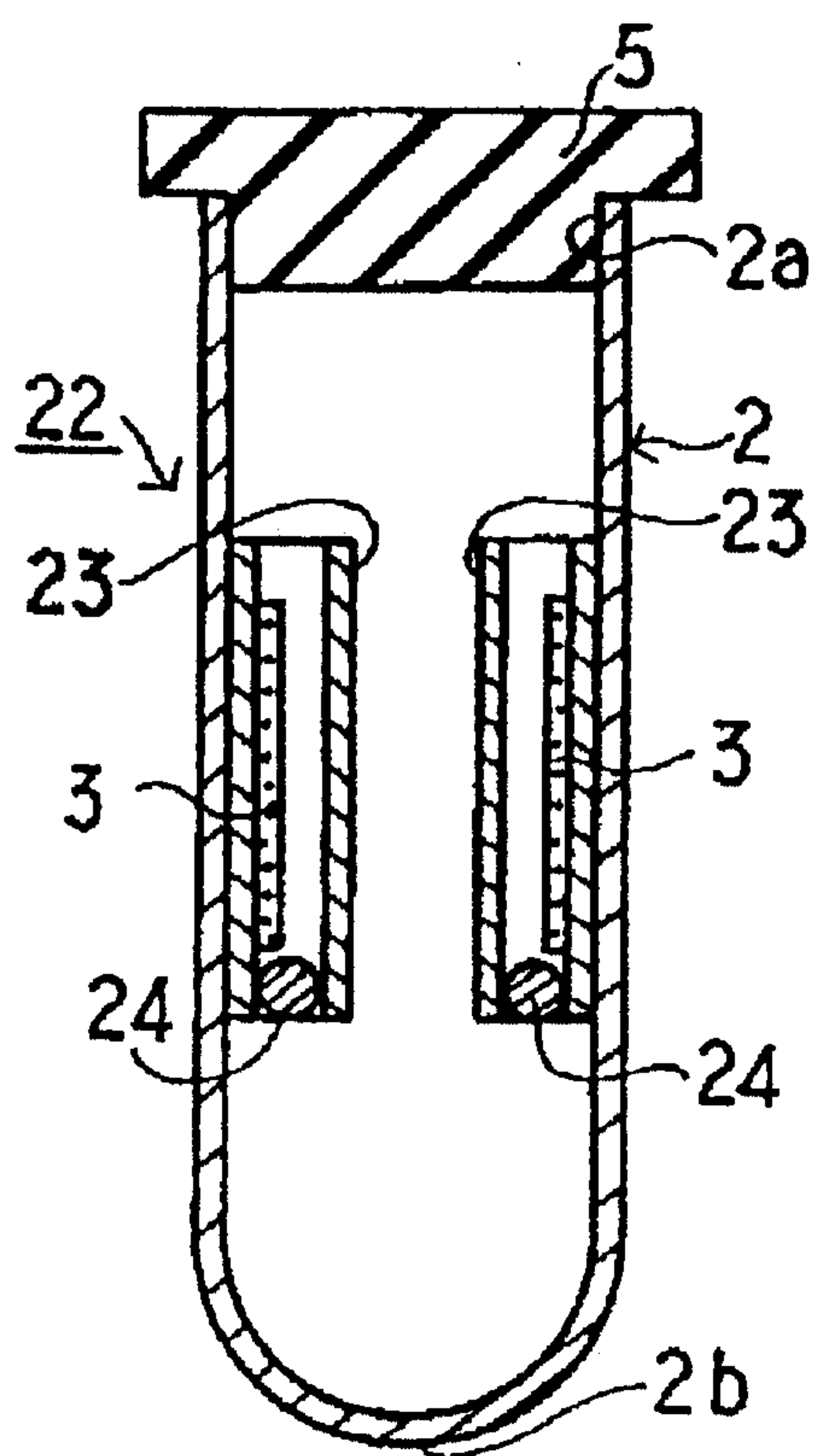


FIG. 25

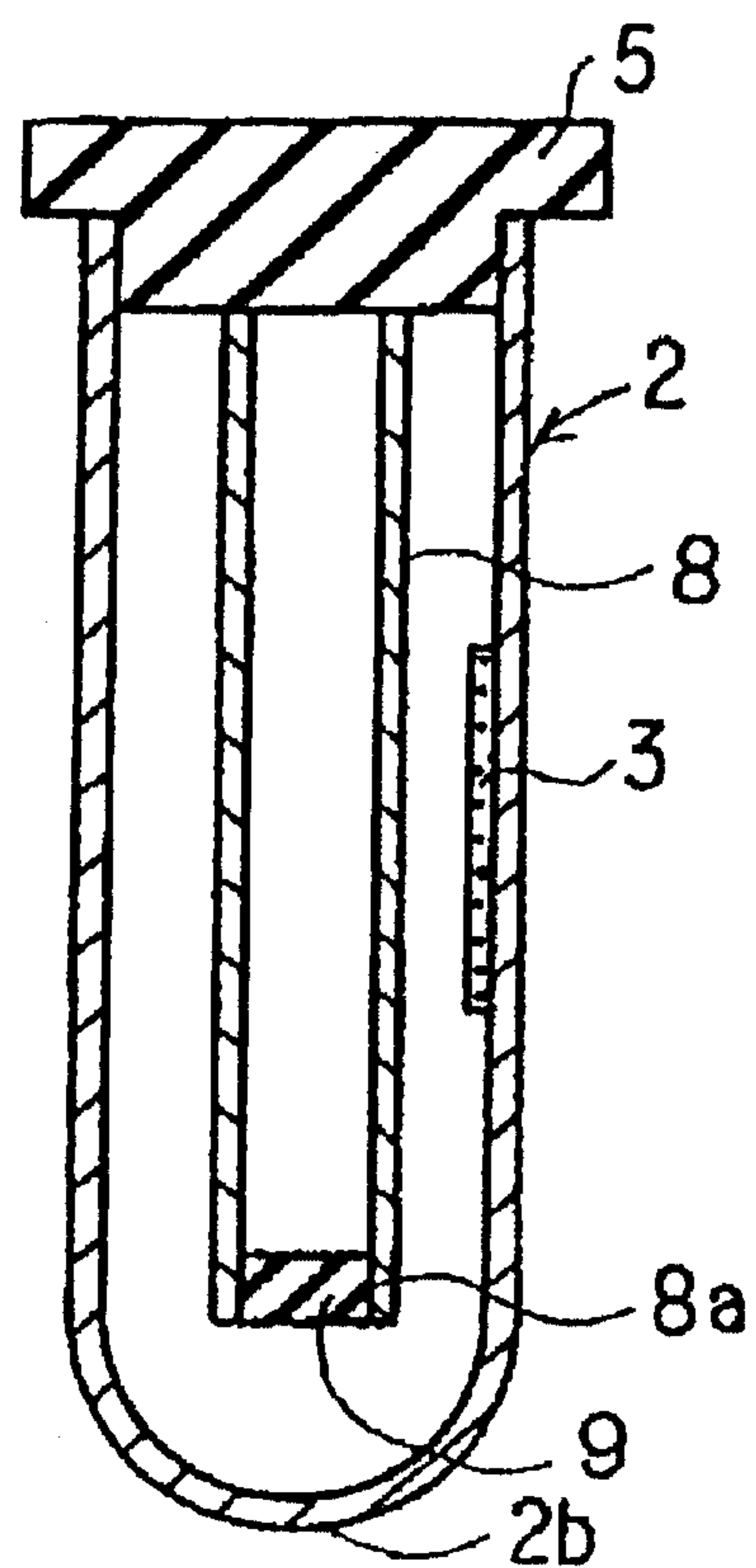


FIG. 26

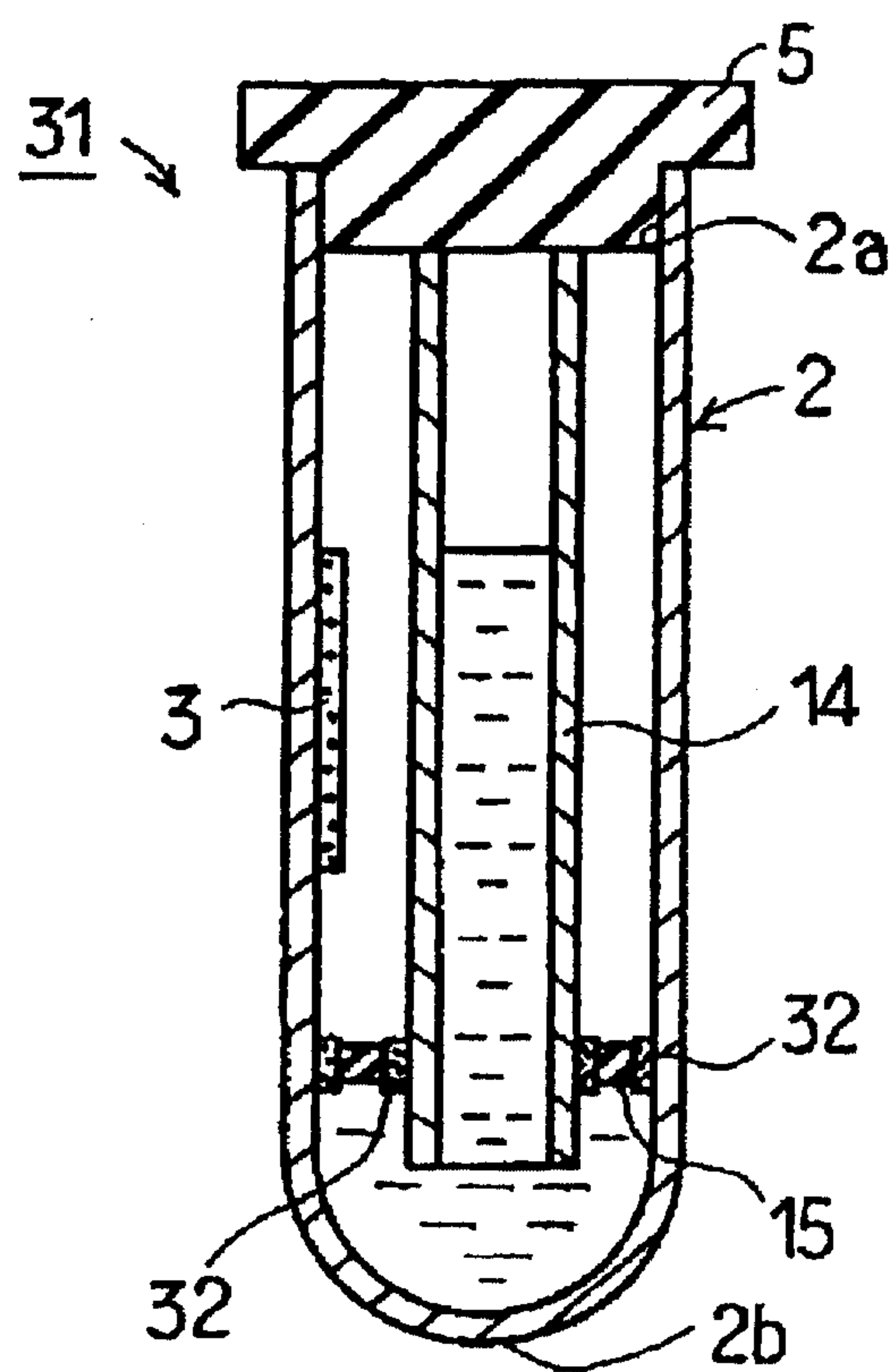


FIG. 27

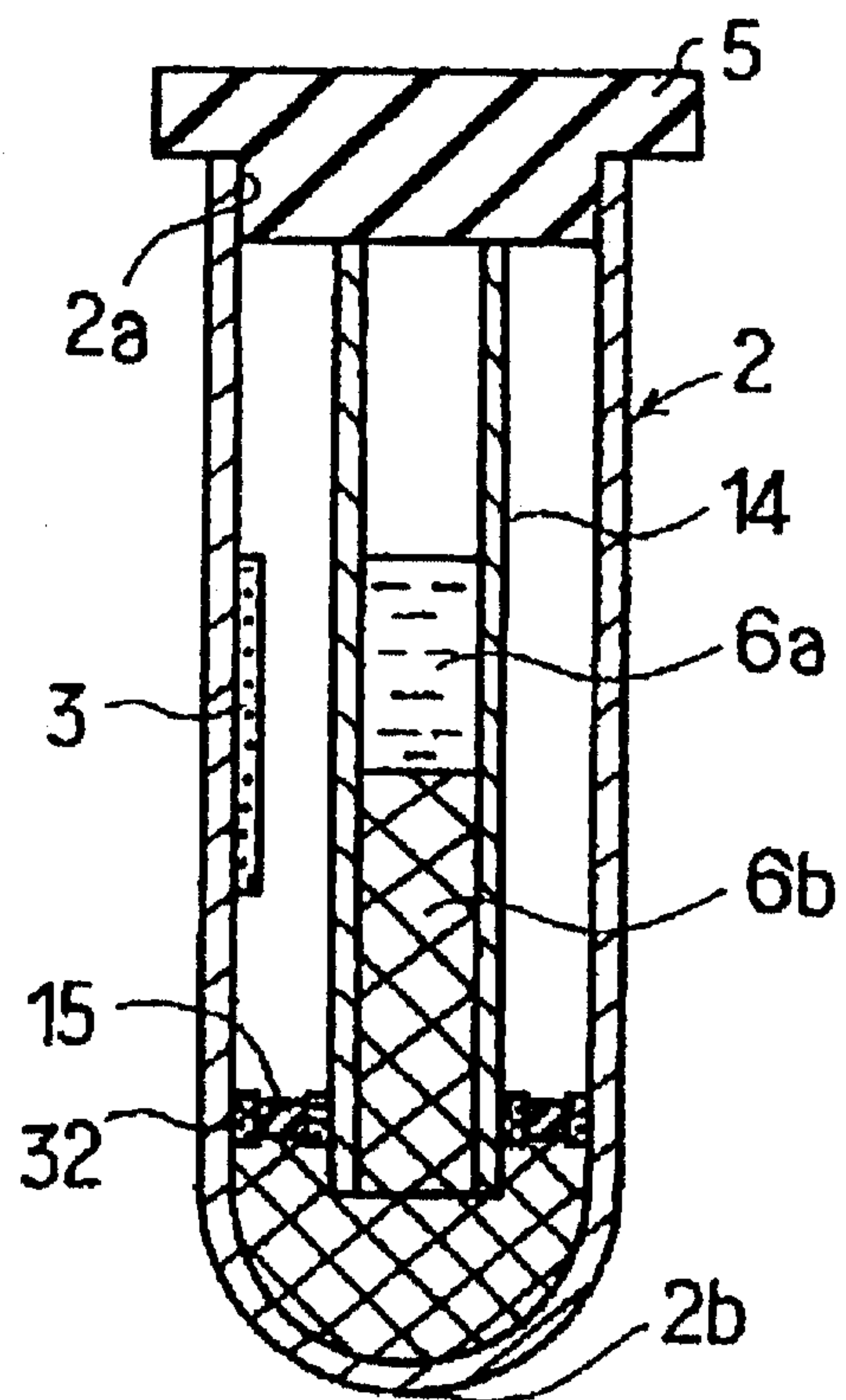


FIG. 28

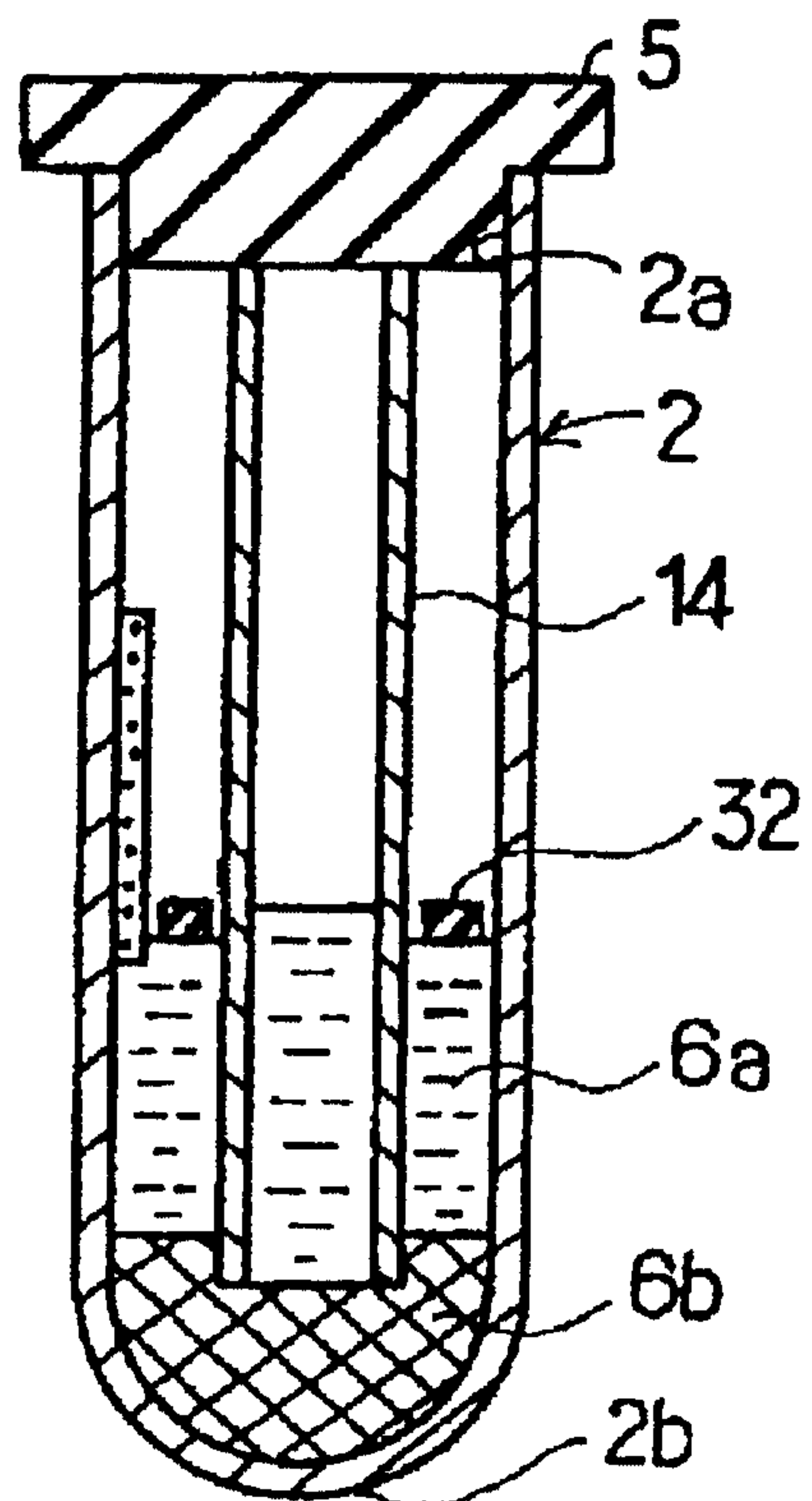


FIG. 29

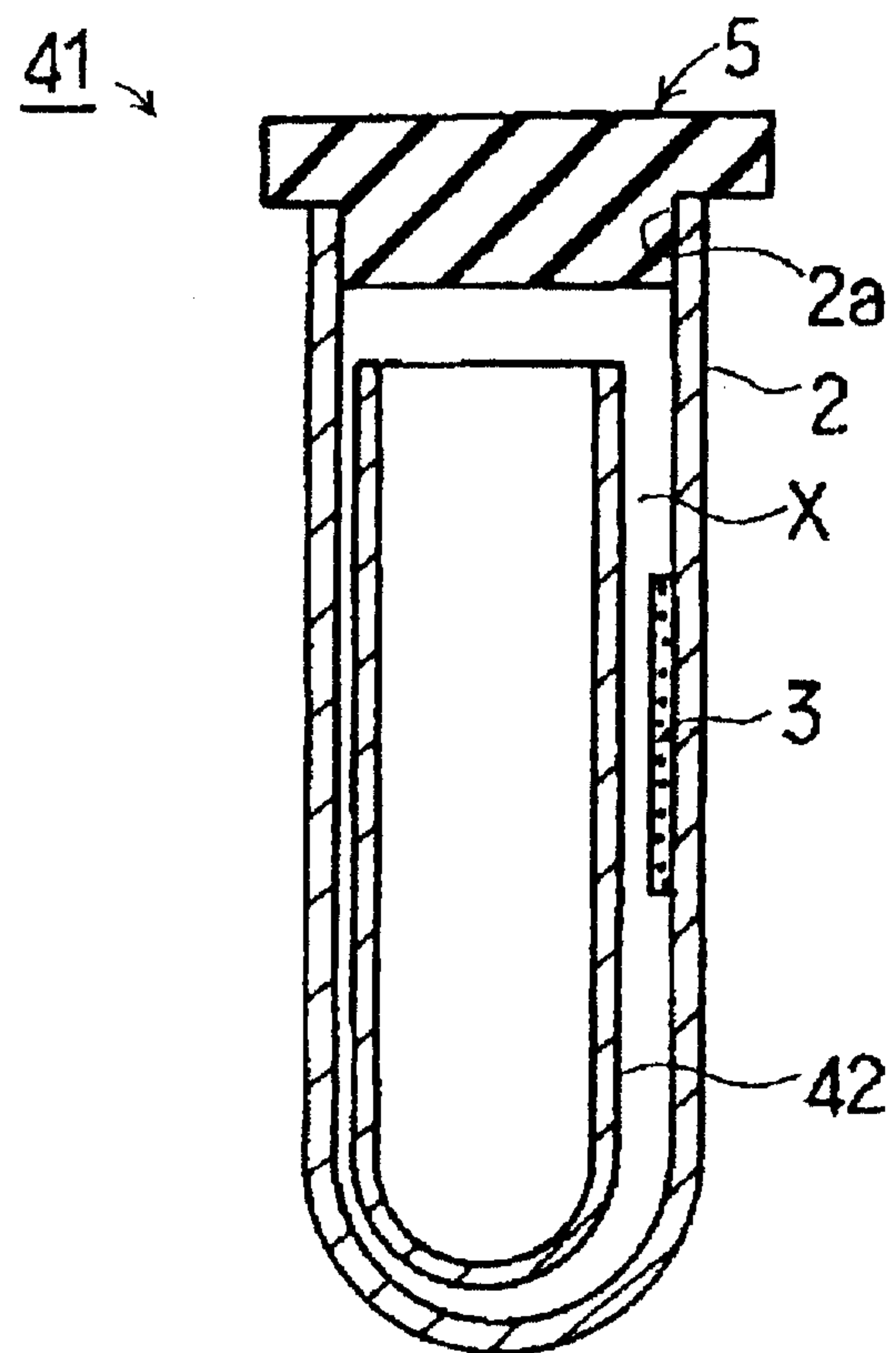


FIG. 30

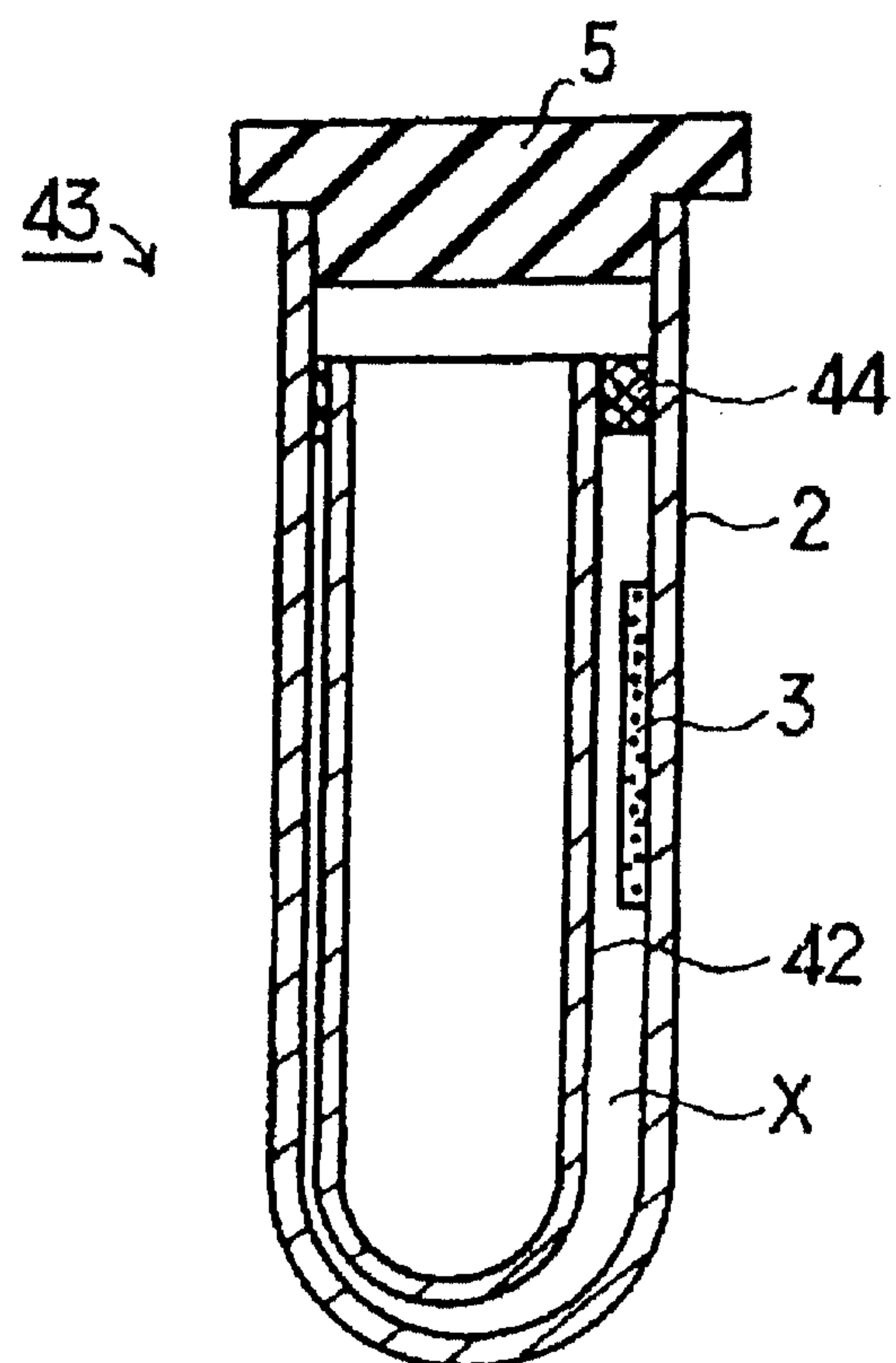


FIG. 31

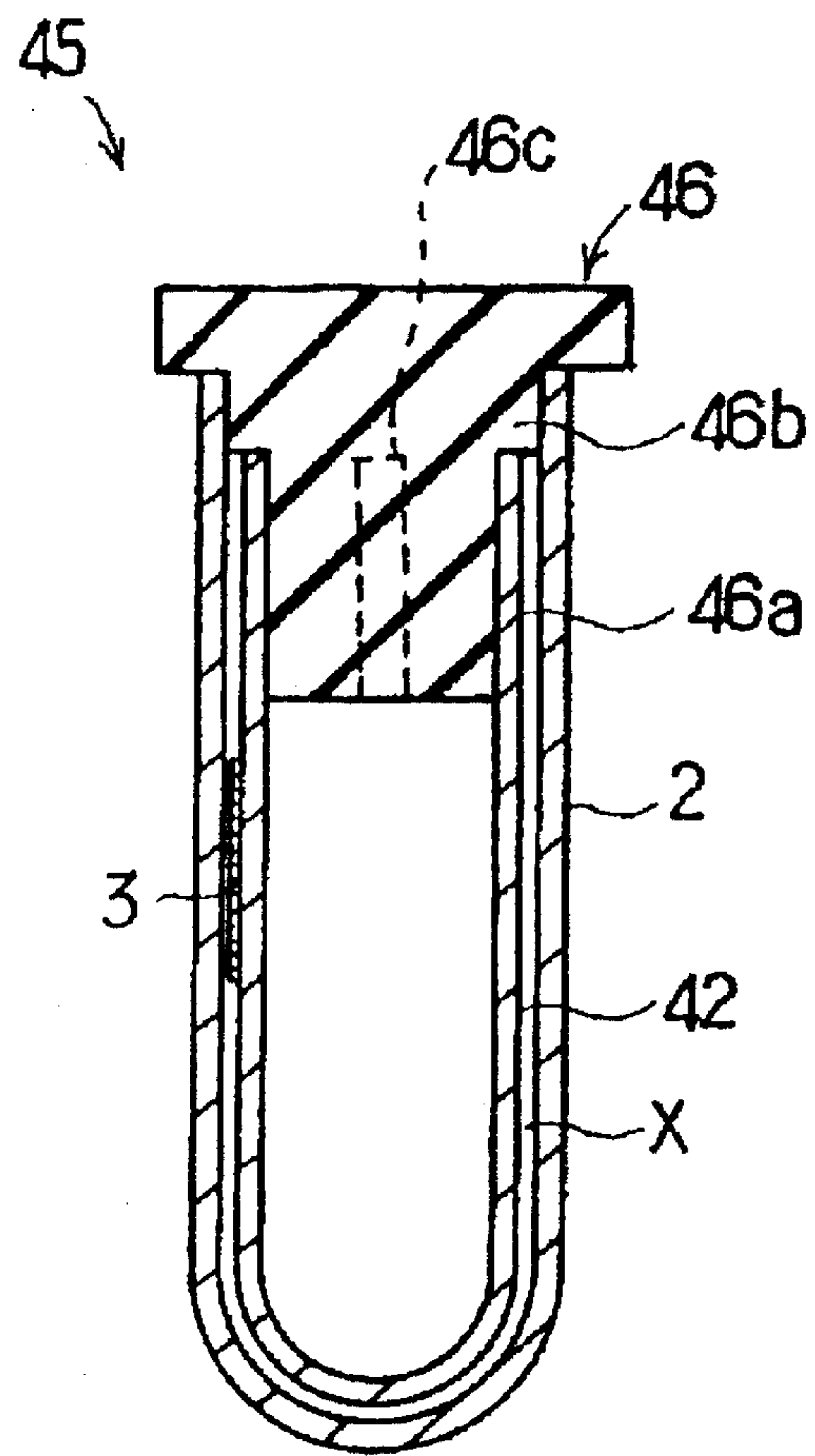


FIG. 32

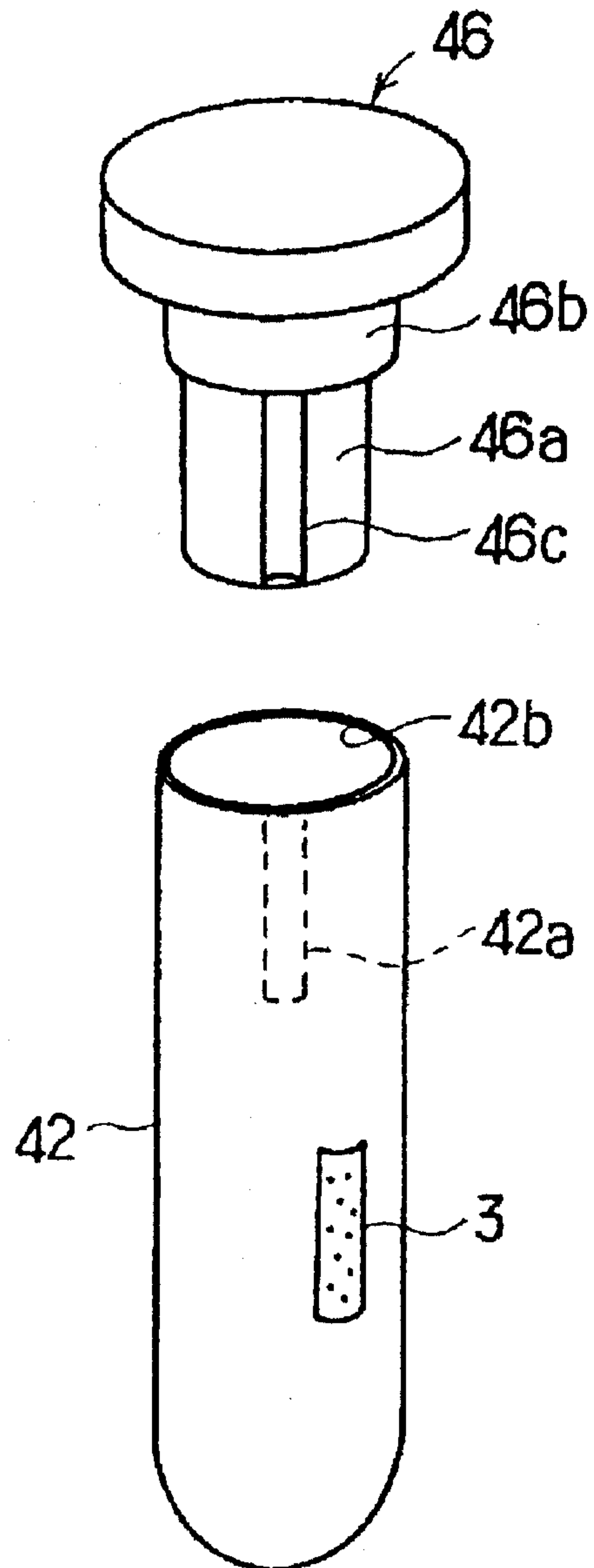


FIG. 33

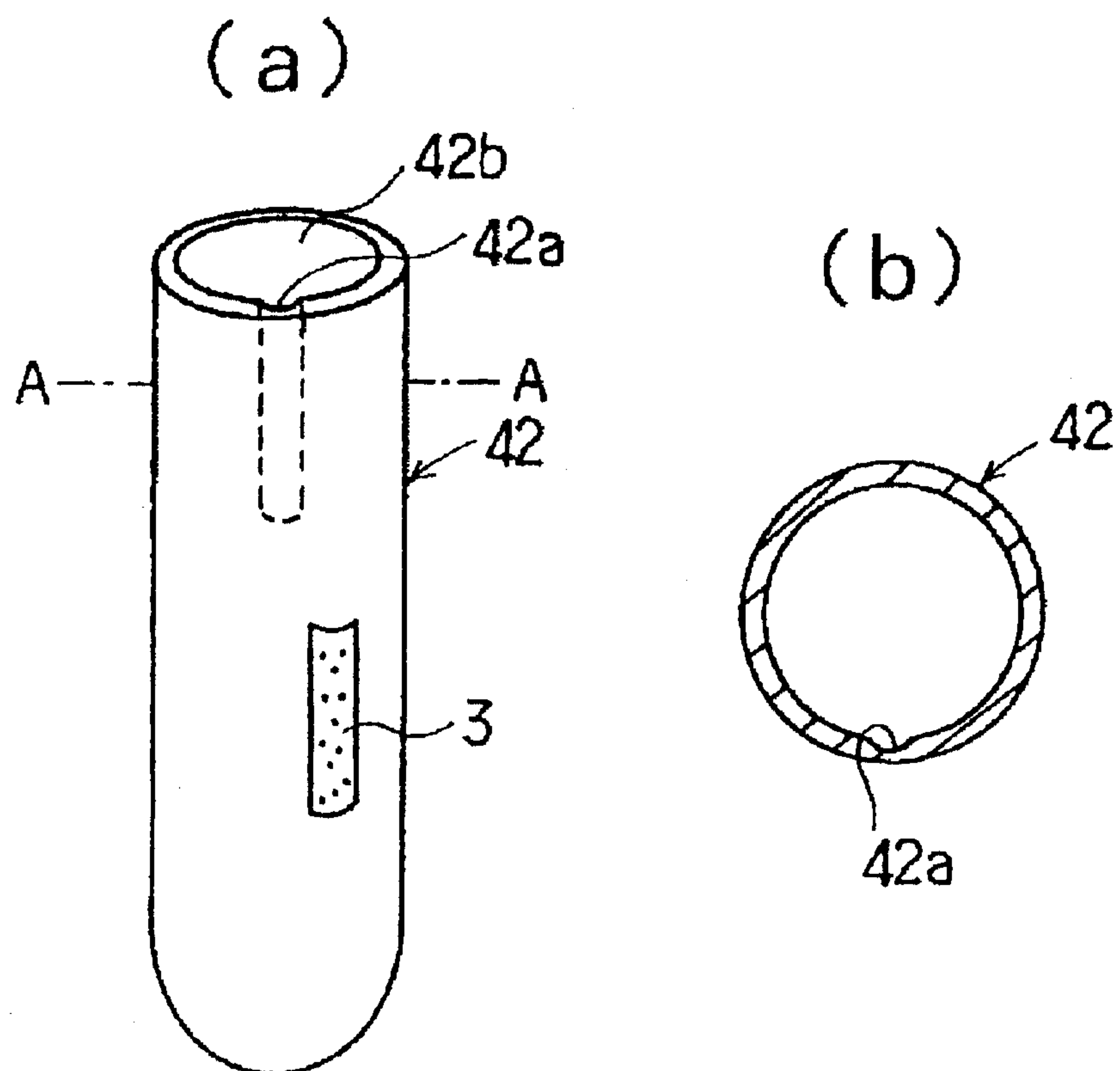


FIG. 34

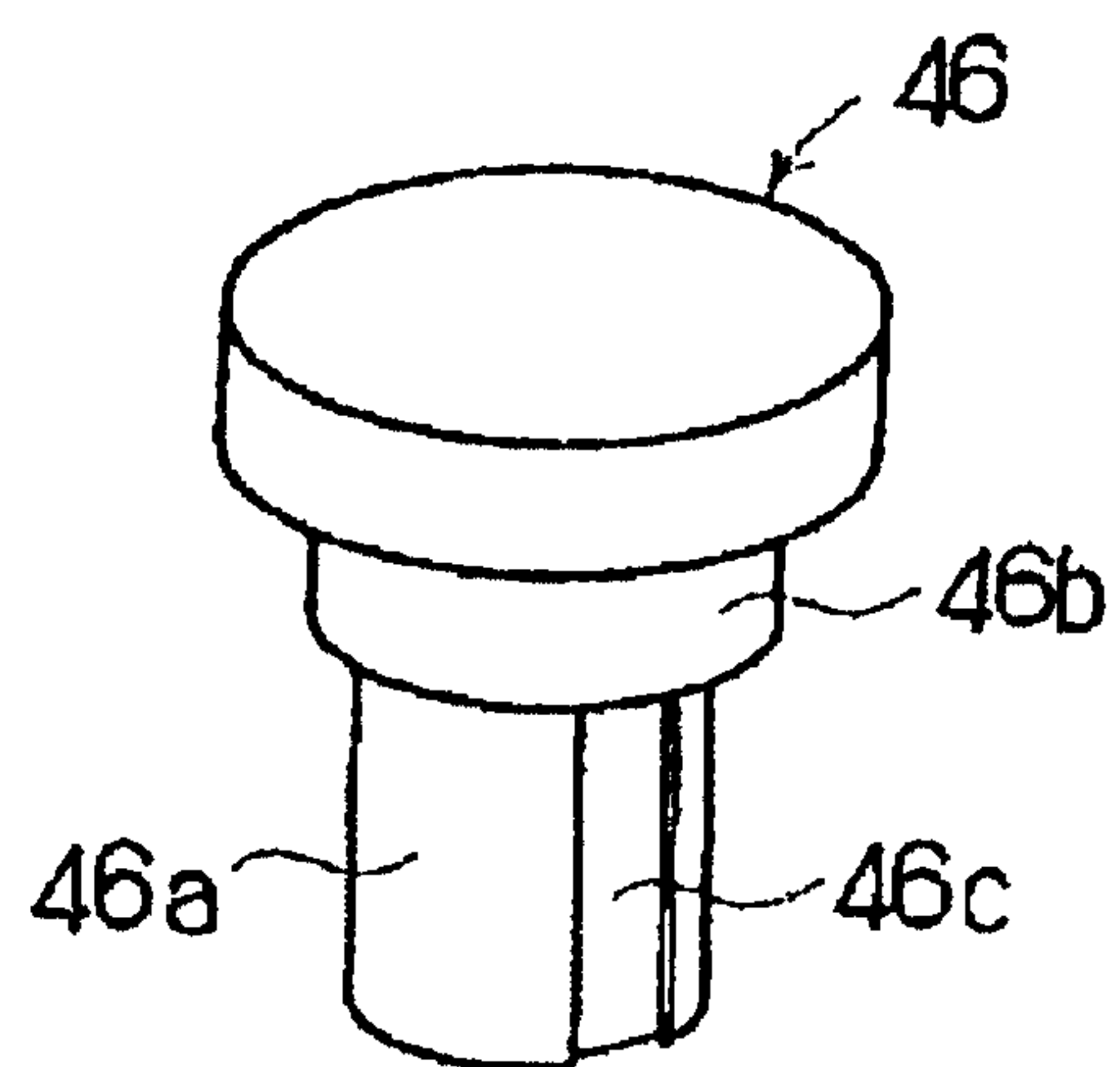


FIG. 35

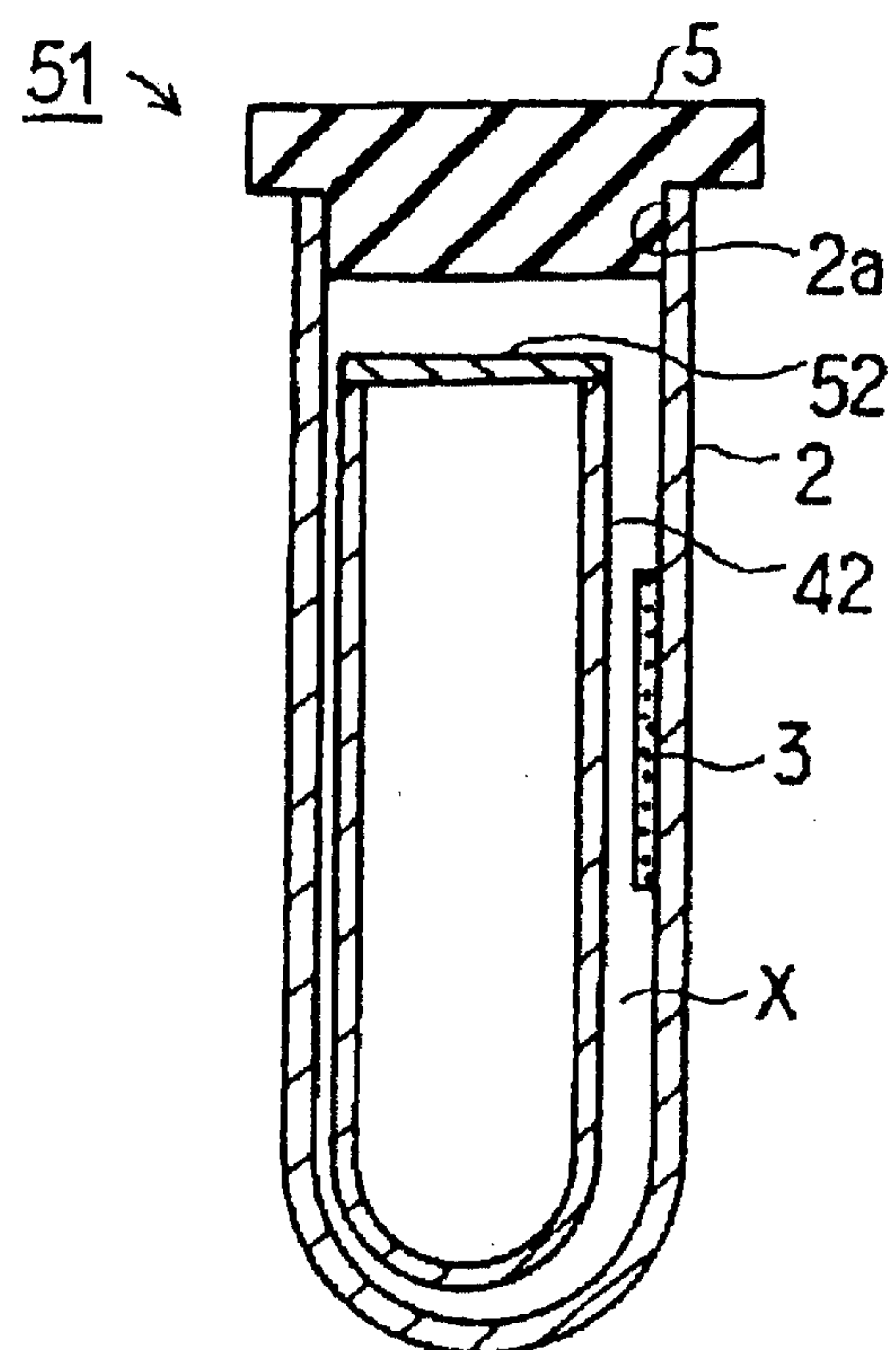


FIG. 36

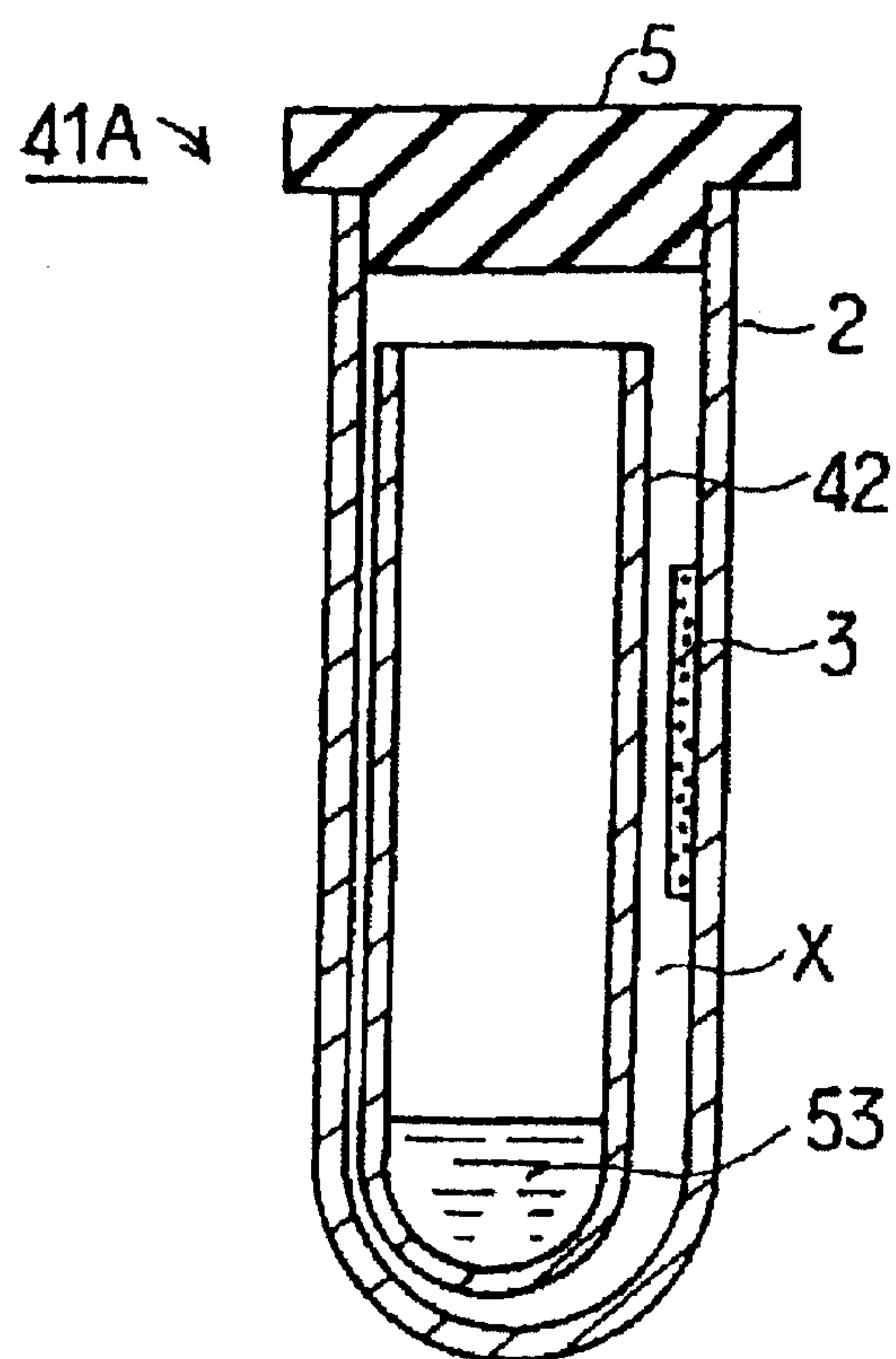


FIG. 37

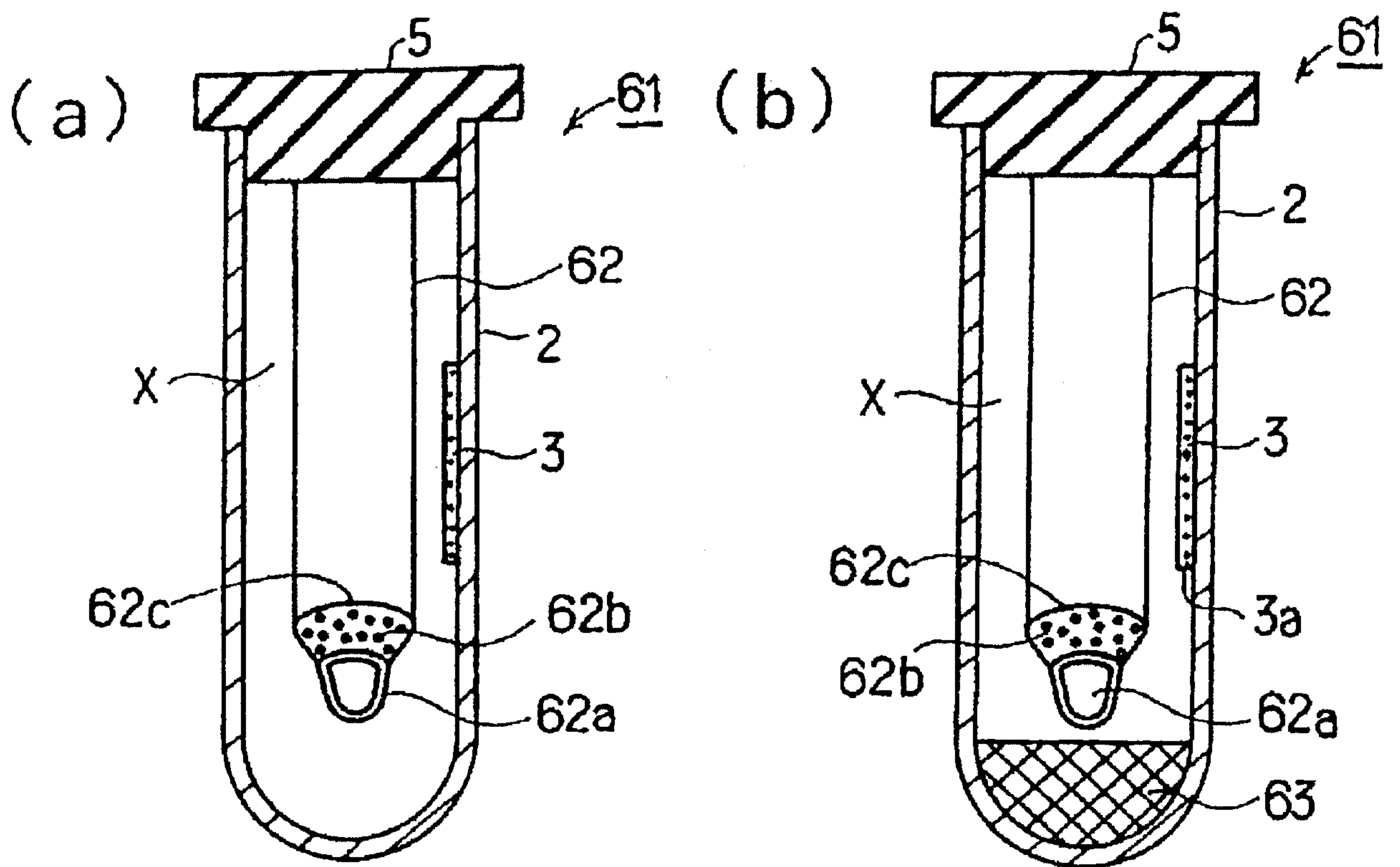


FIG. 38

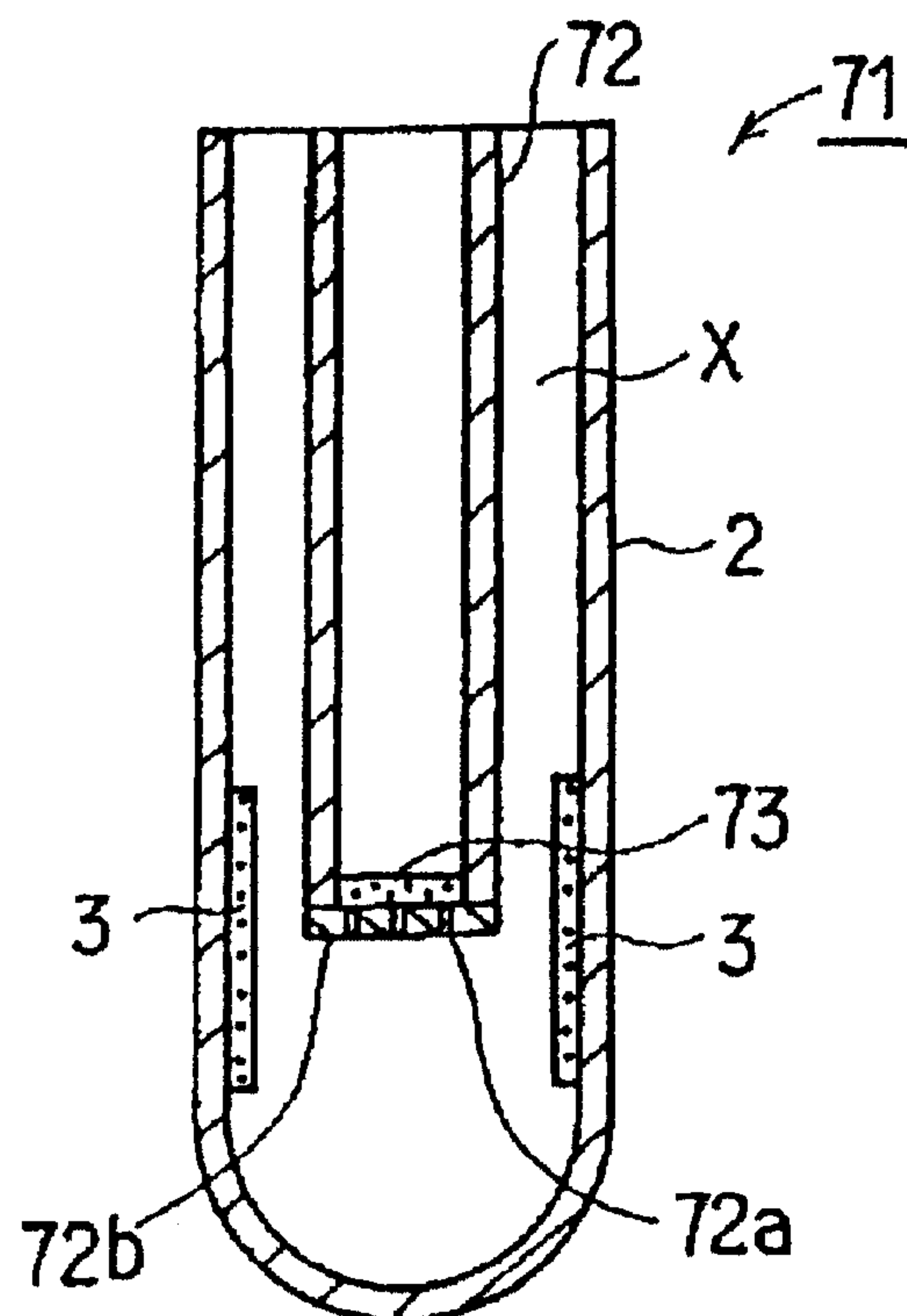


FIG. 39

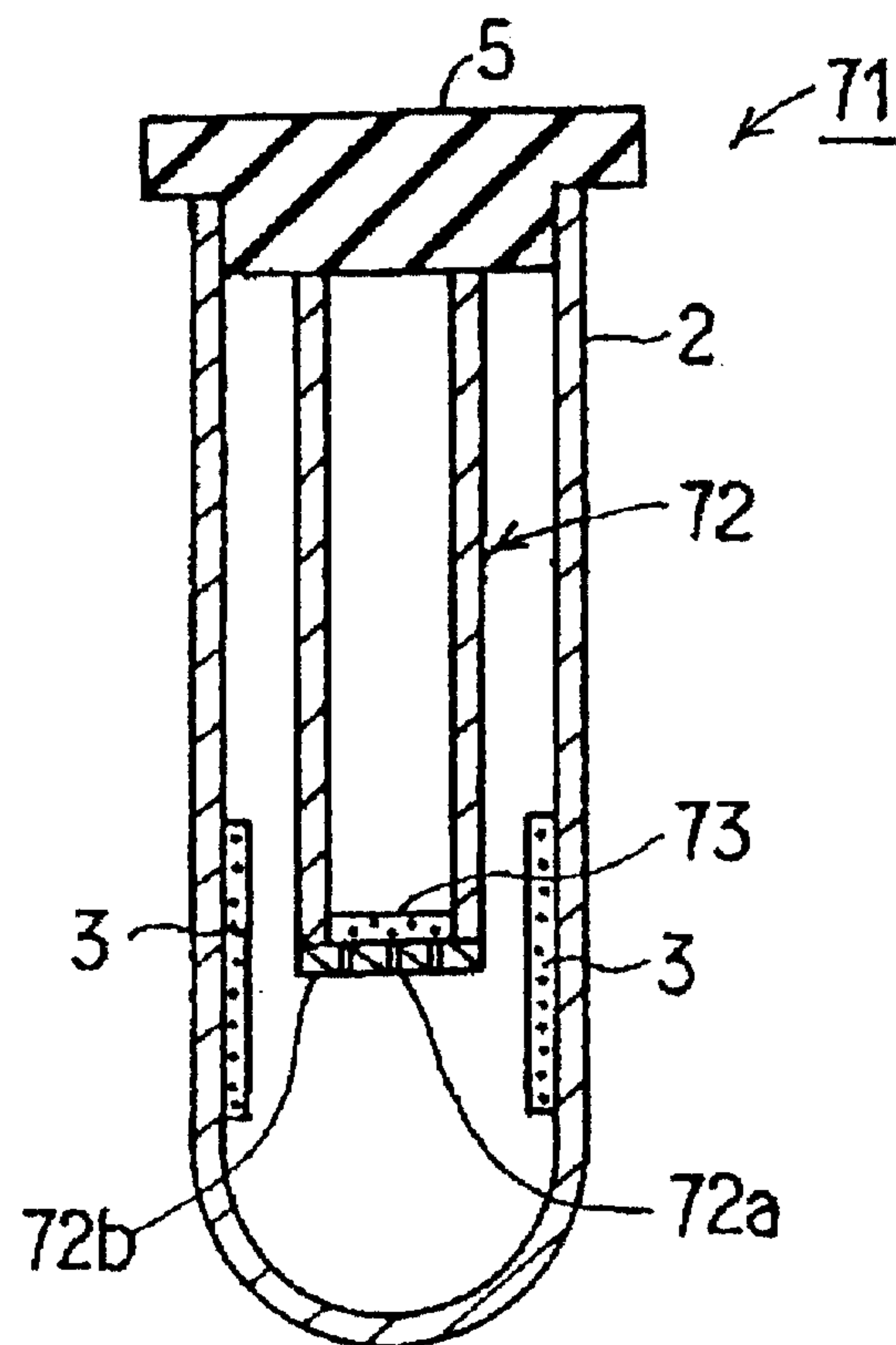


FIG. 40

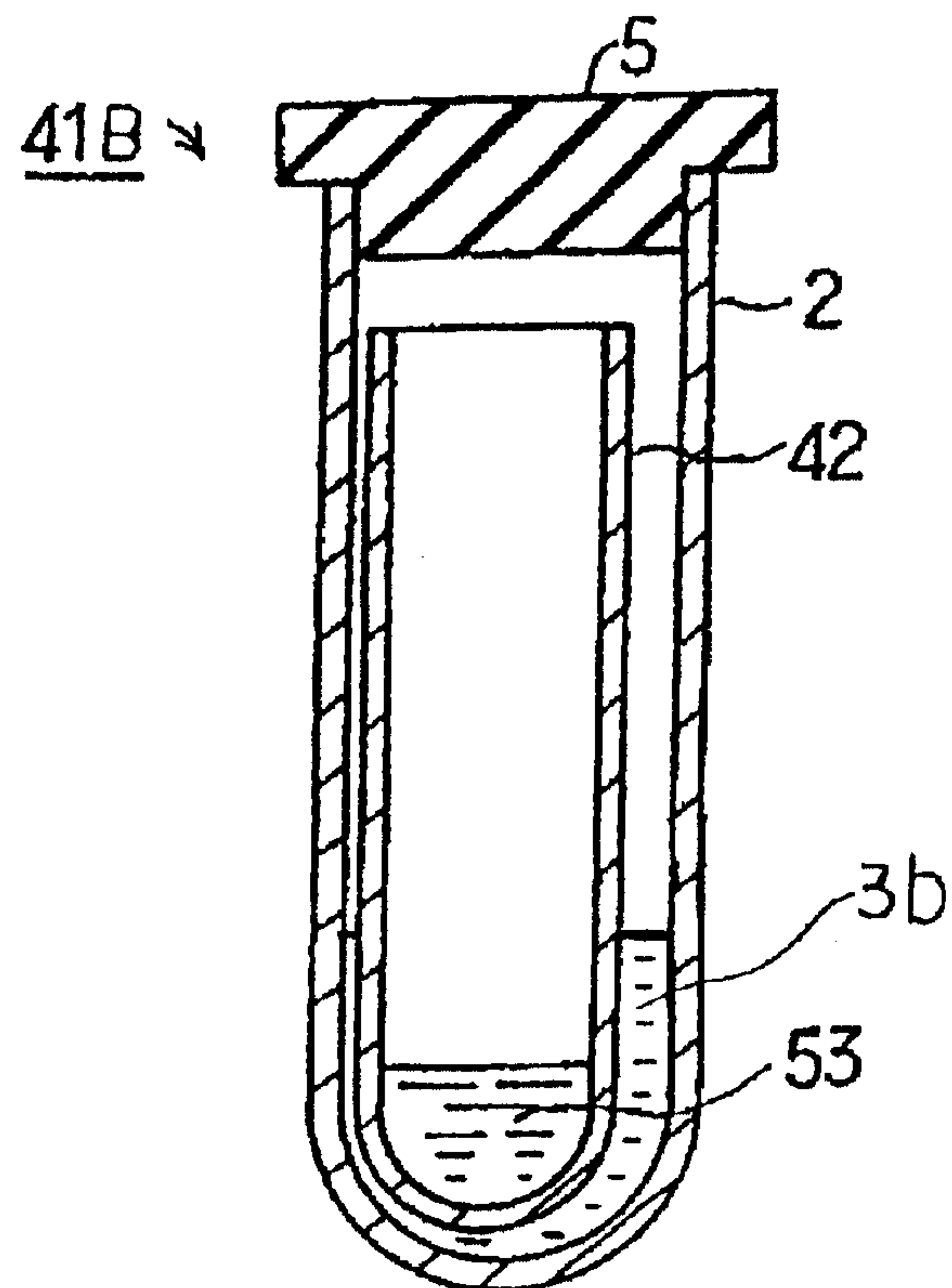


FIG. 41

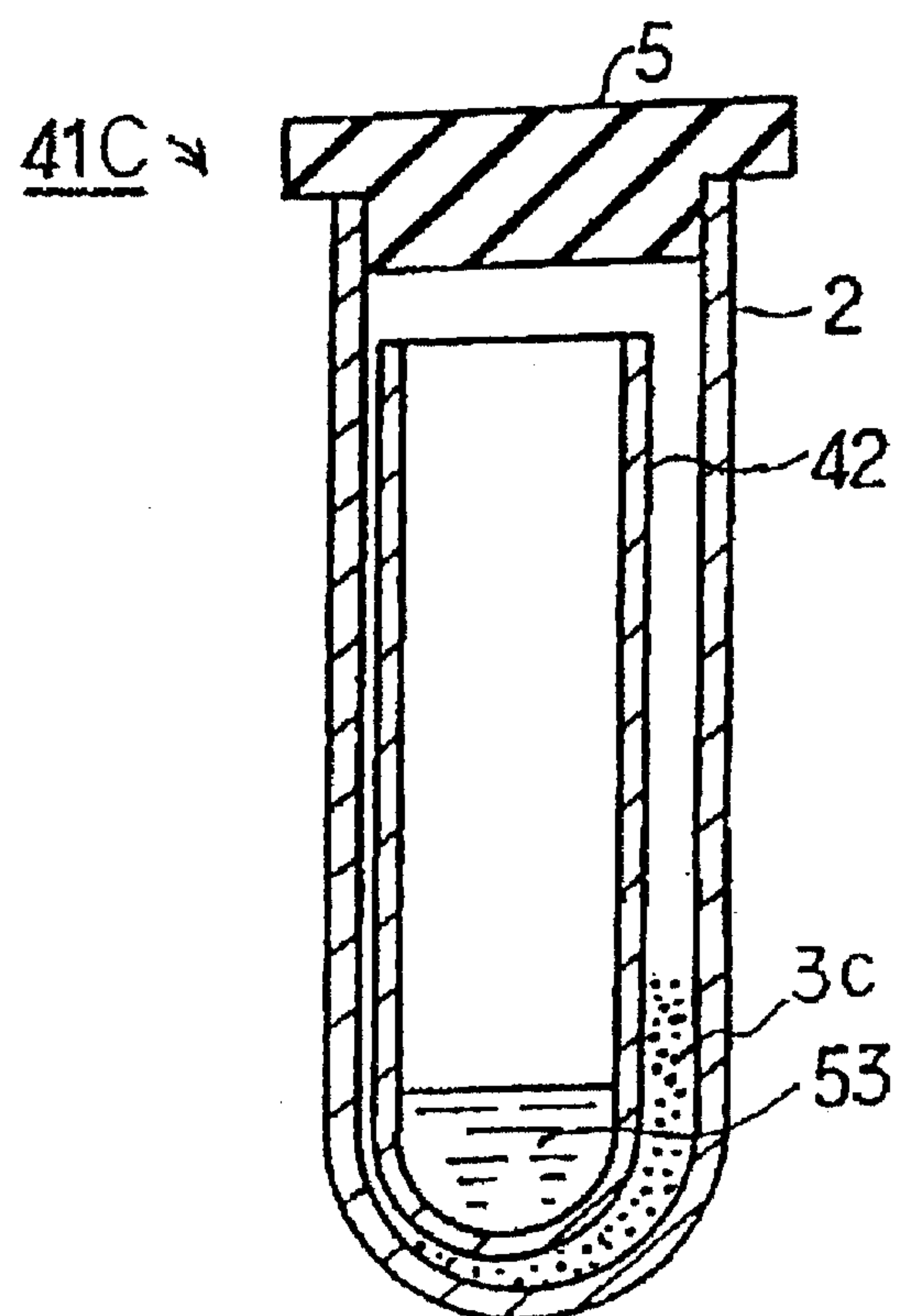


FIG. 42

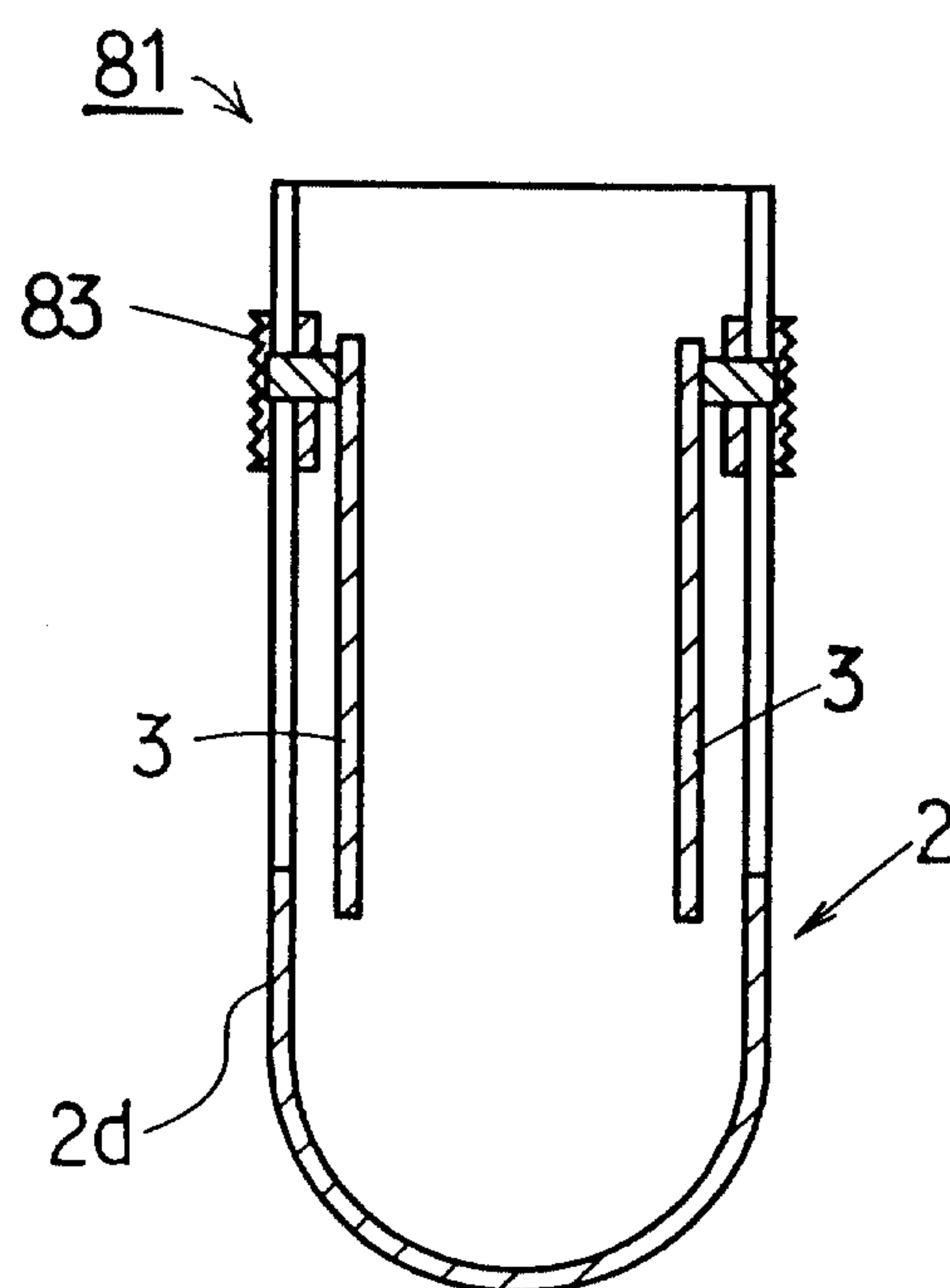


FIG. 43

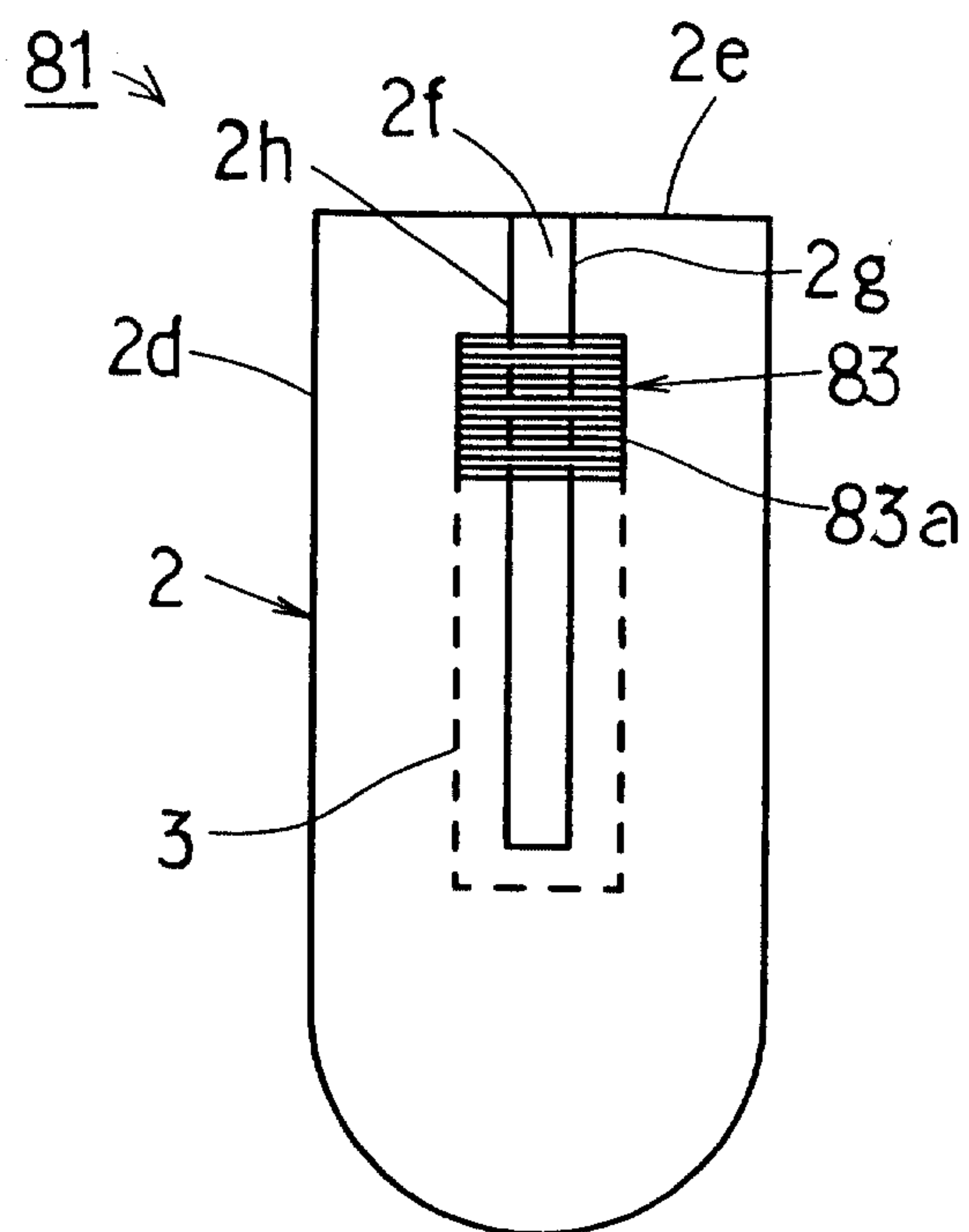


FIG. 44

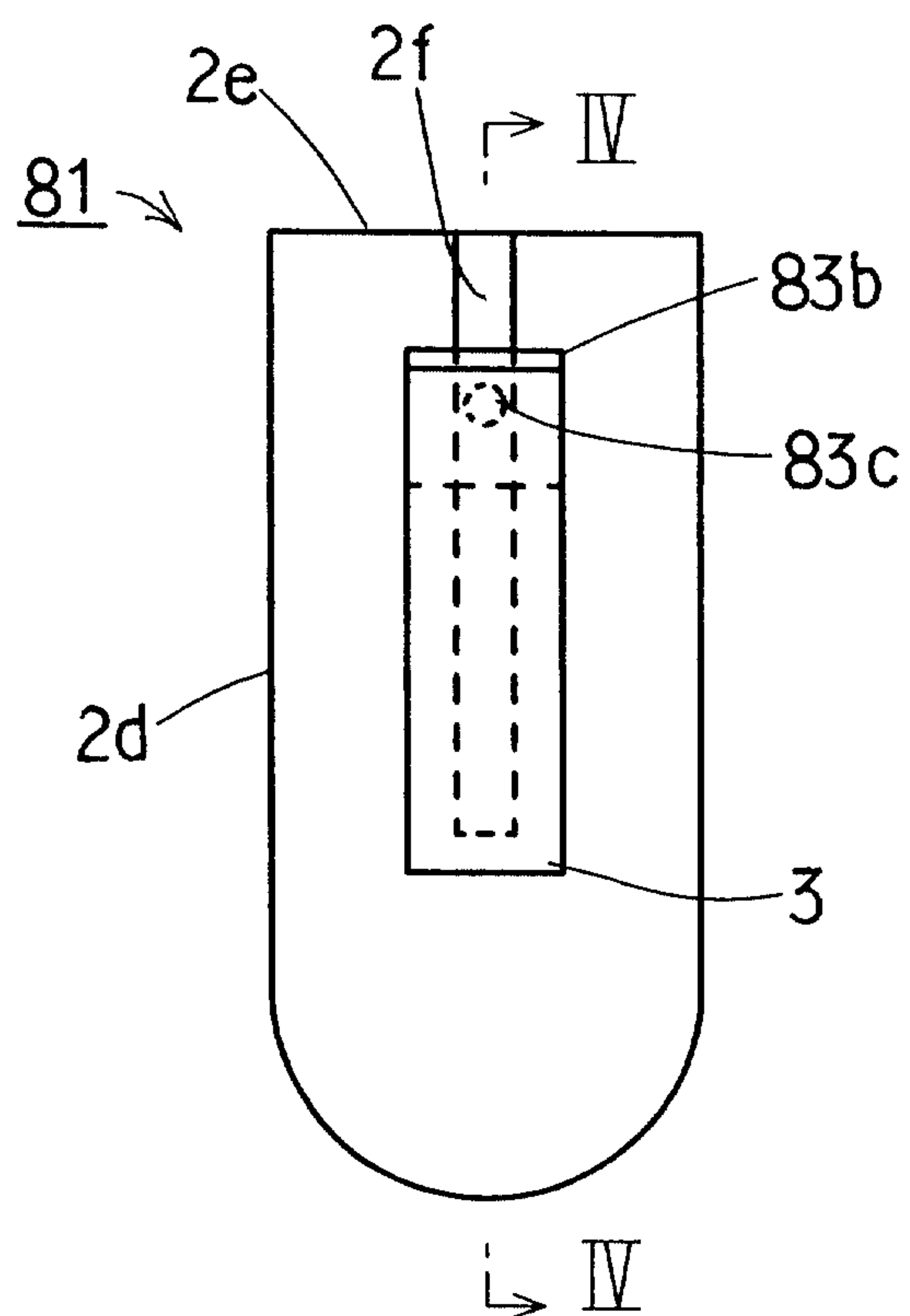


FIG. 45

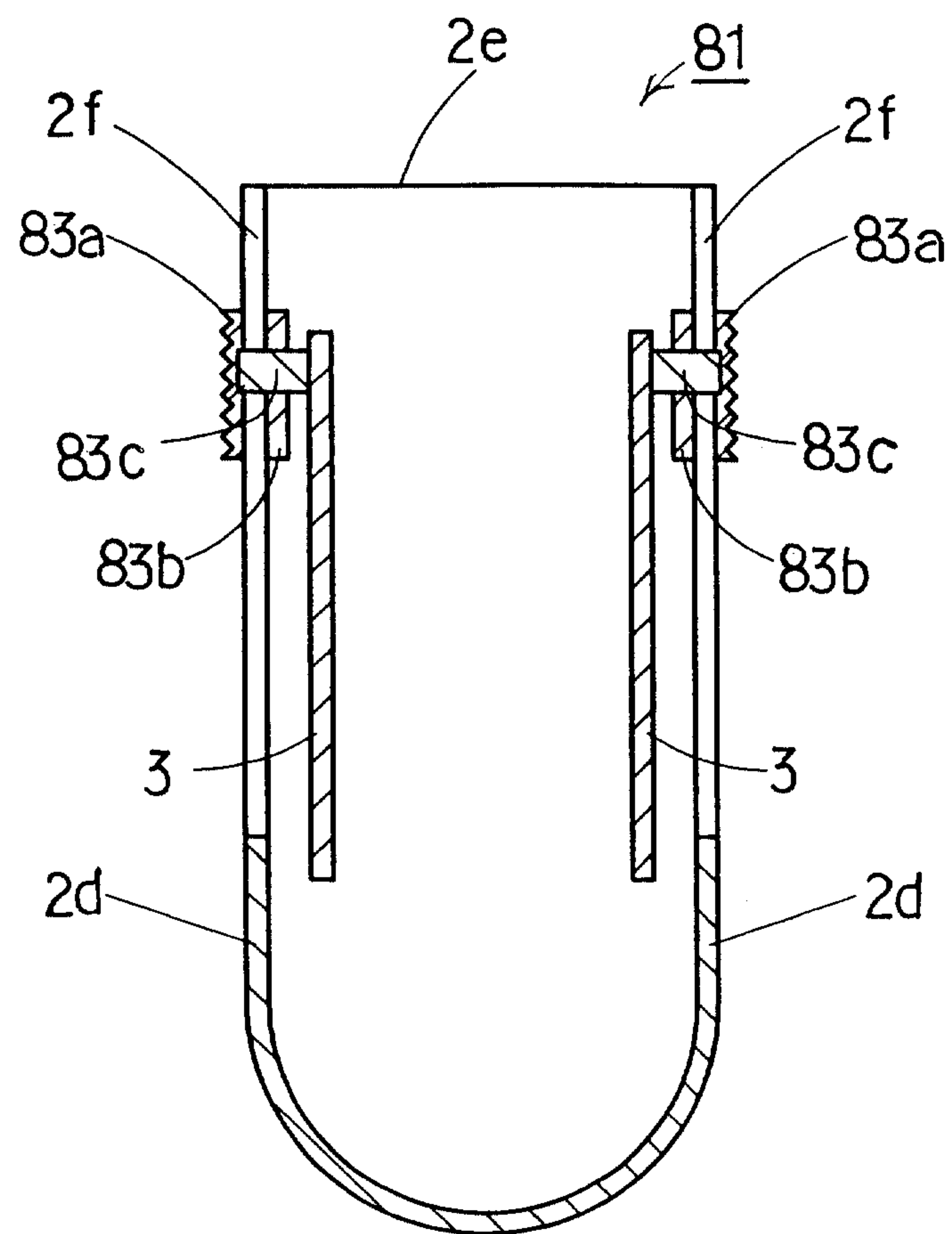


FIG. 46

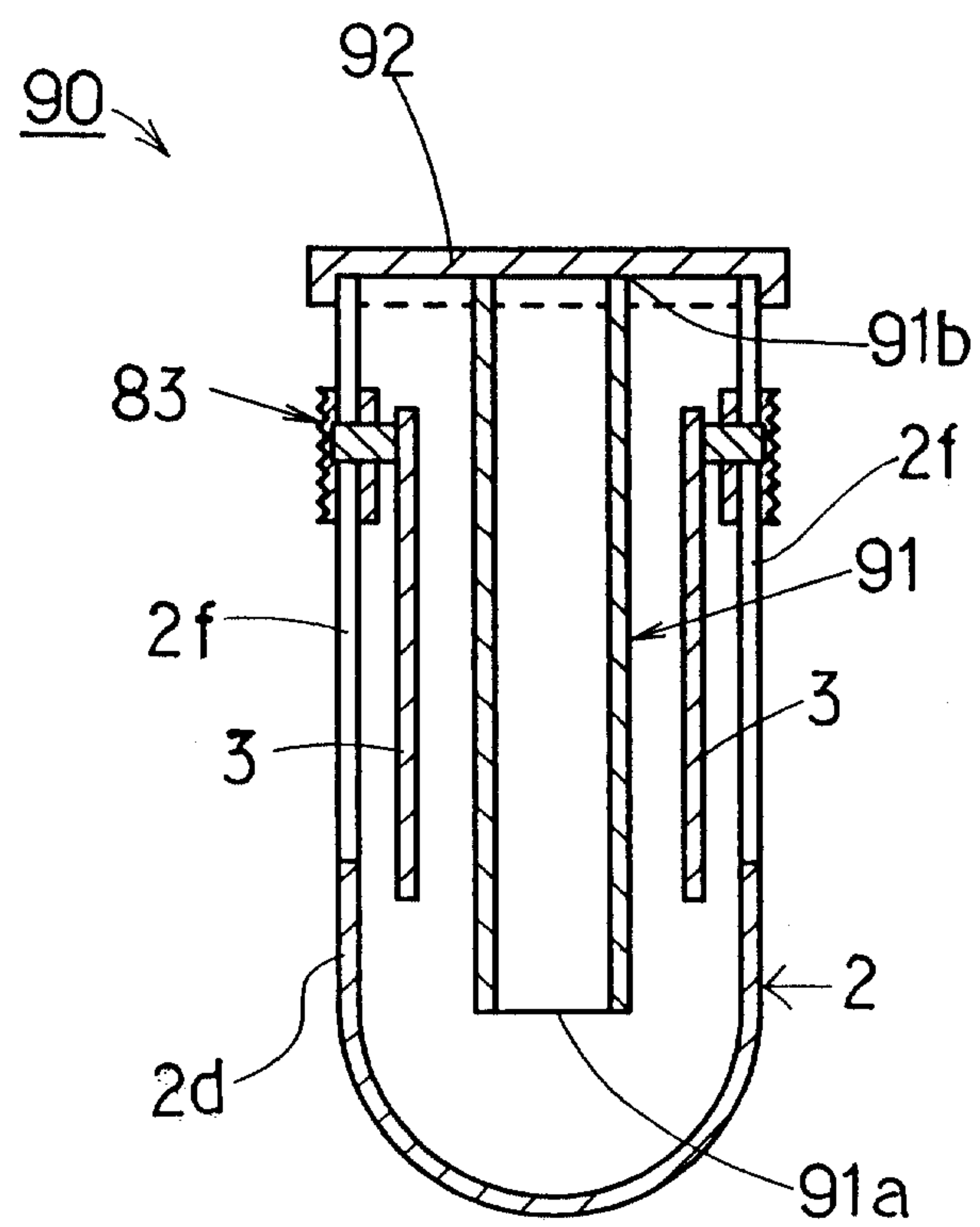


FIG. 47

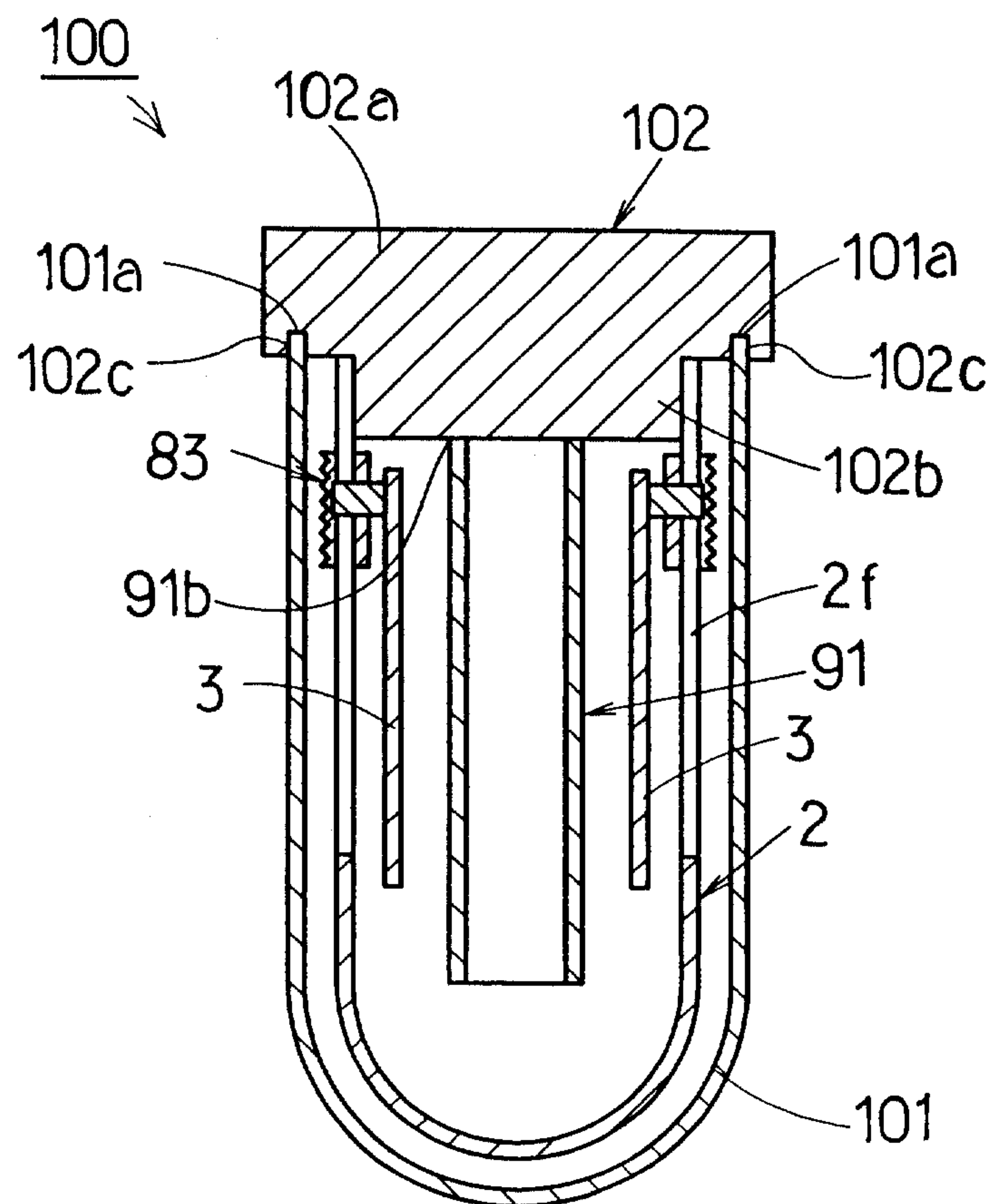


FIG. 48

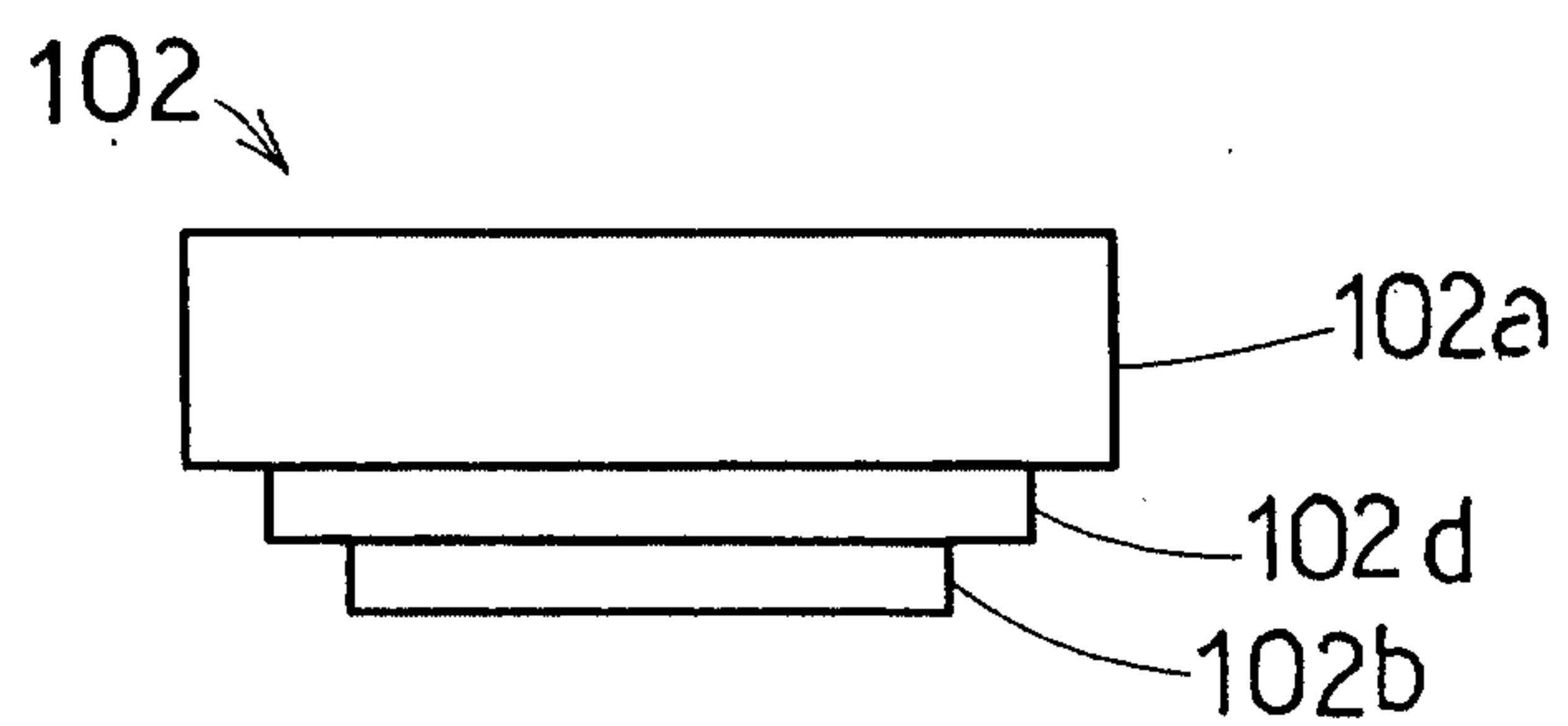


FIG. 49

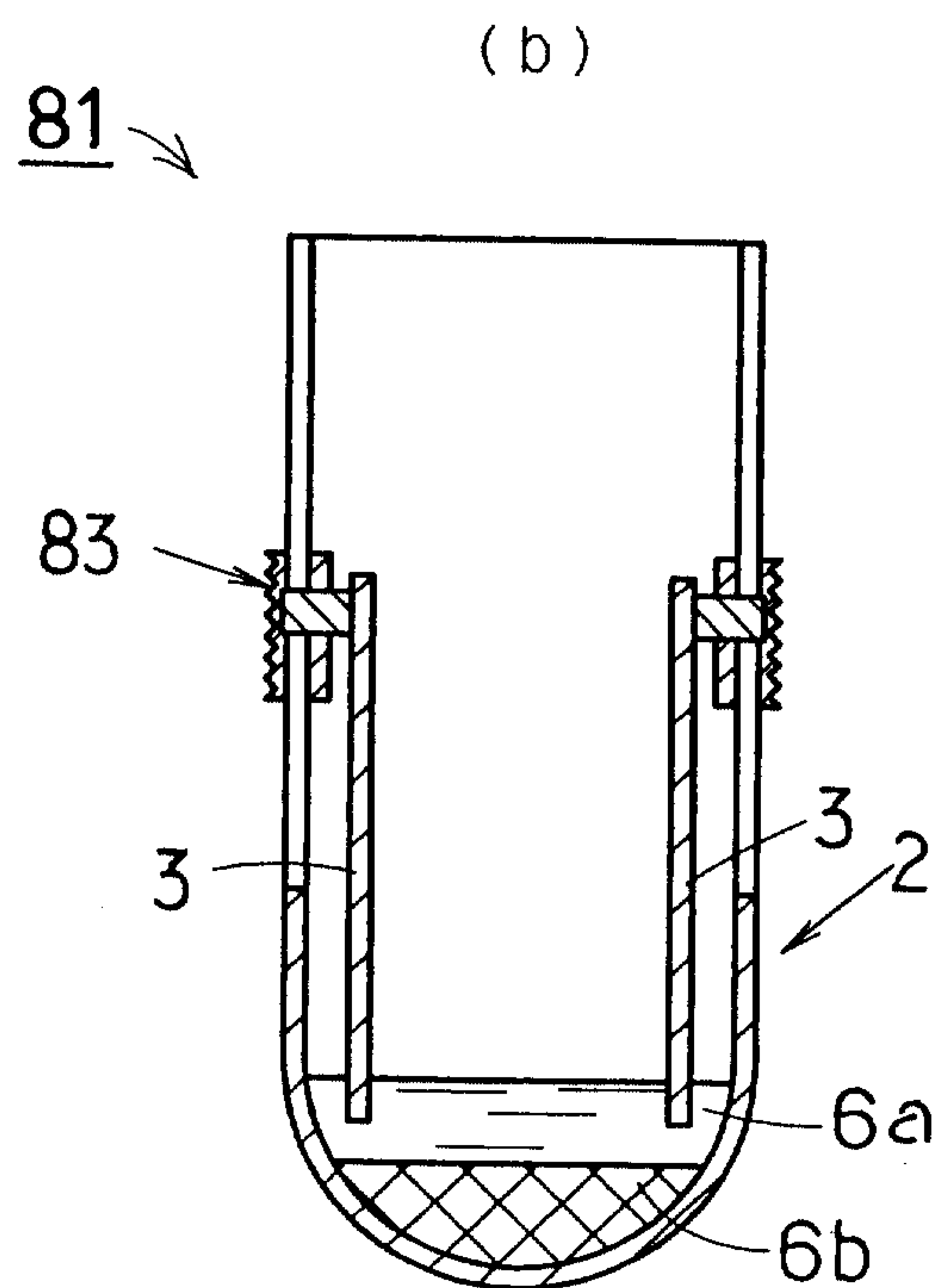
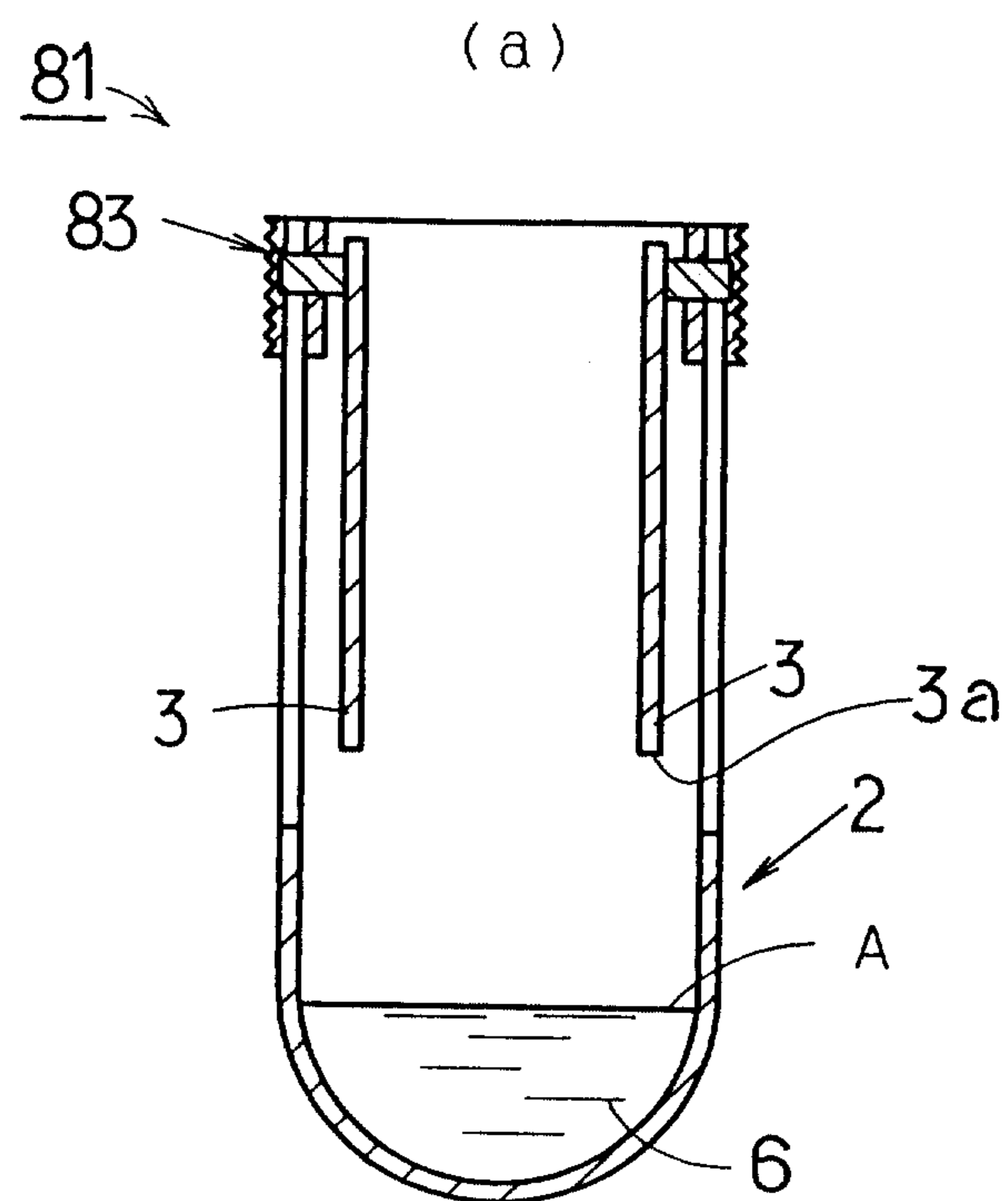


FIG. 50

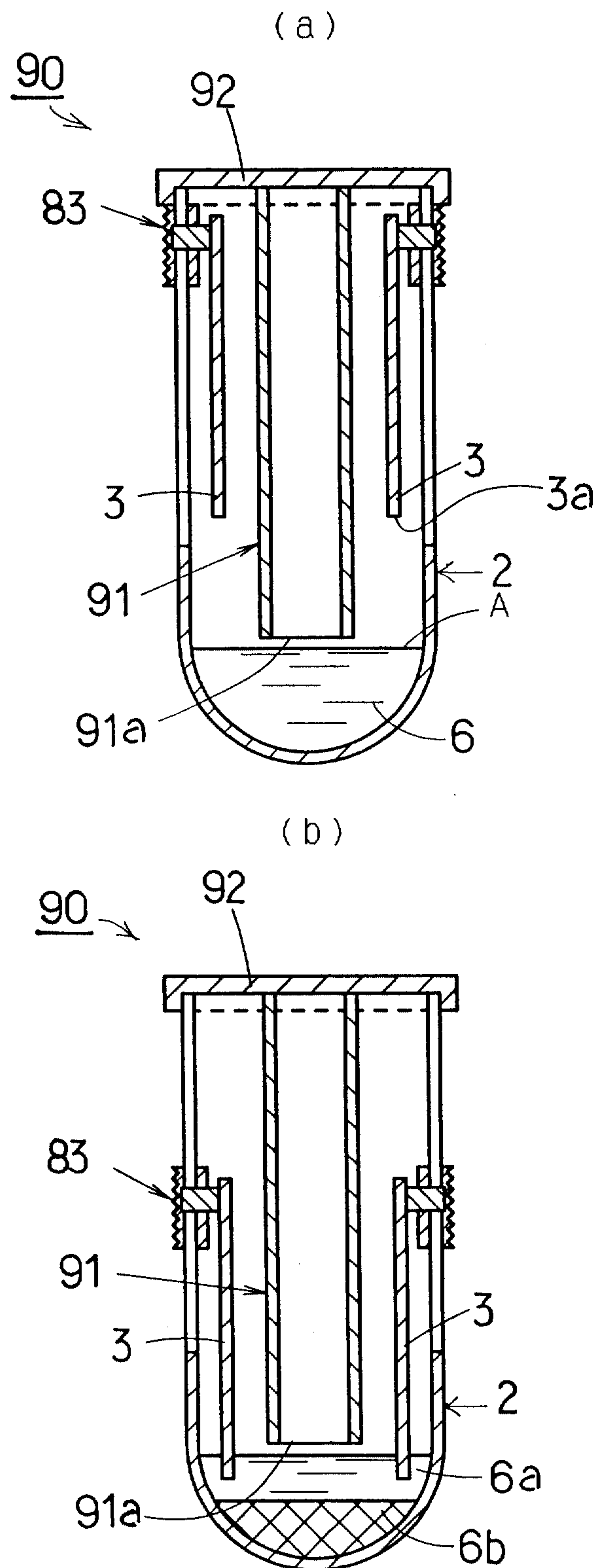


FIG. 51

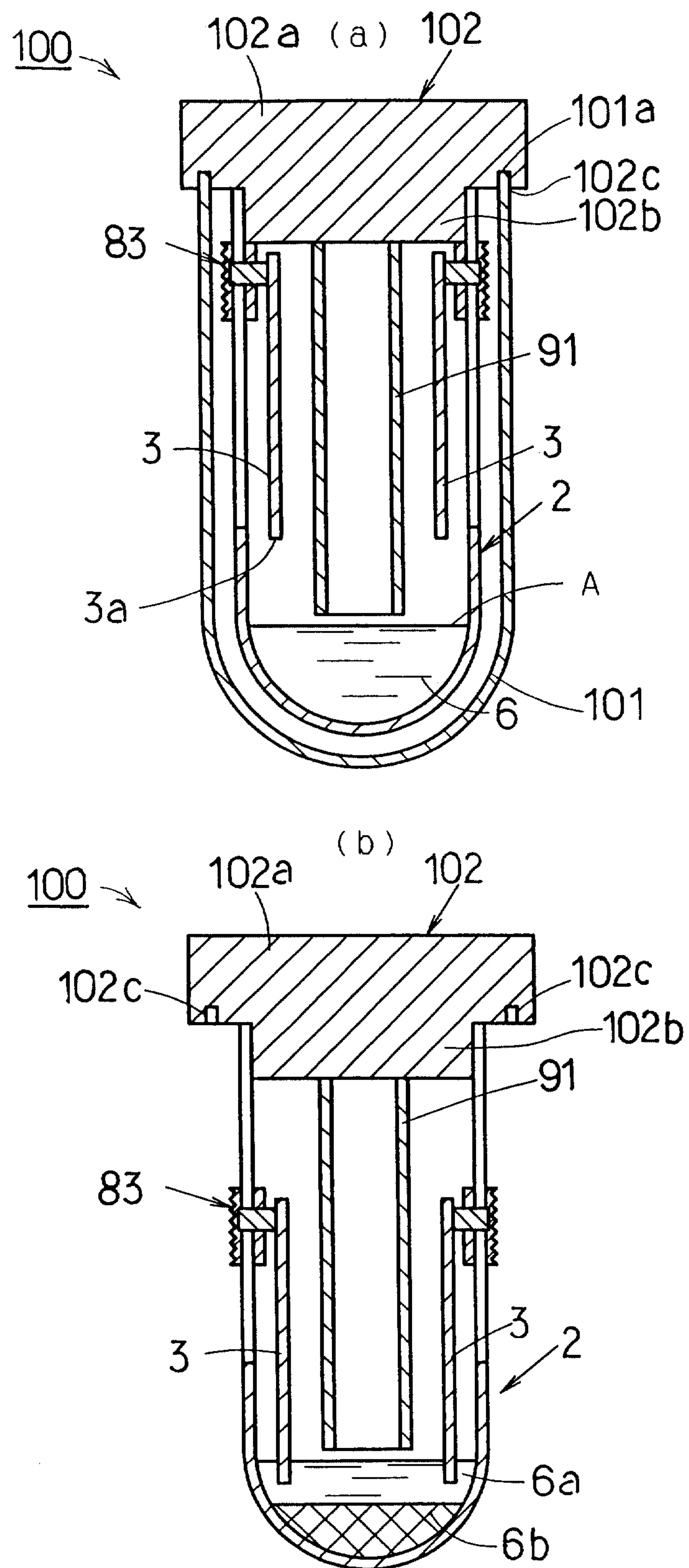


FIG. 52

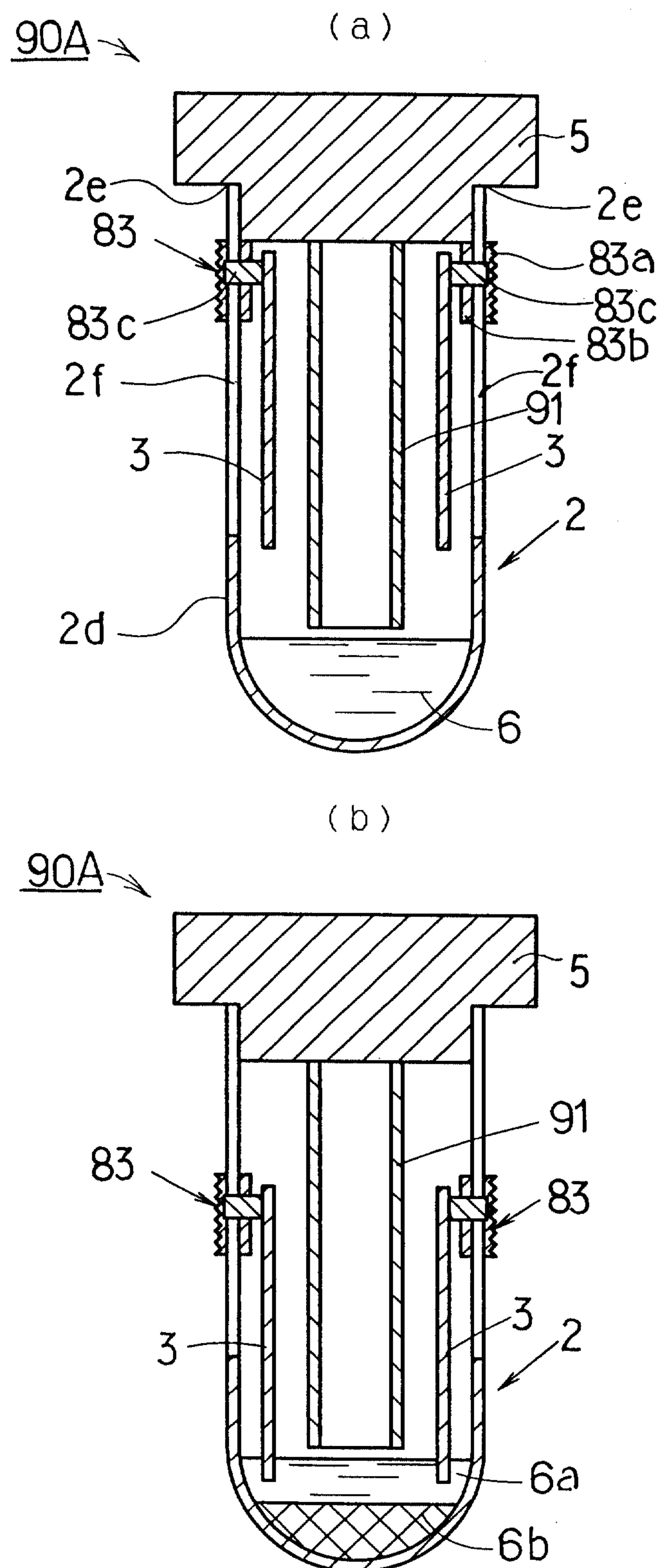


FIG. 53

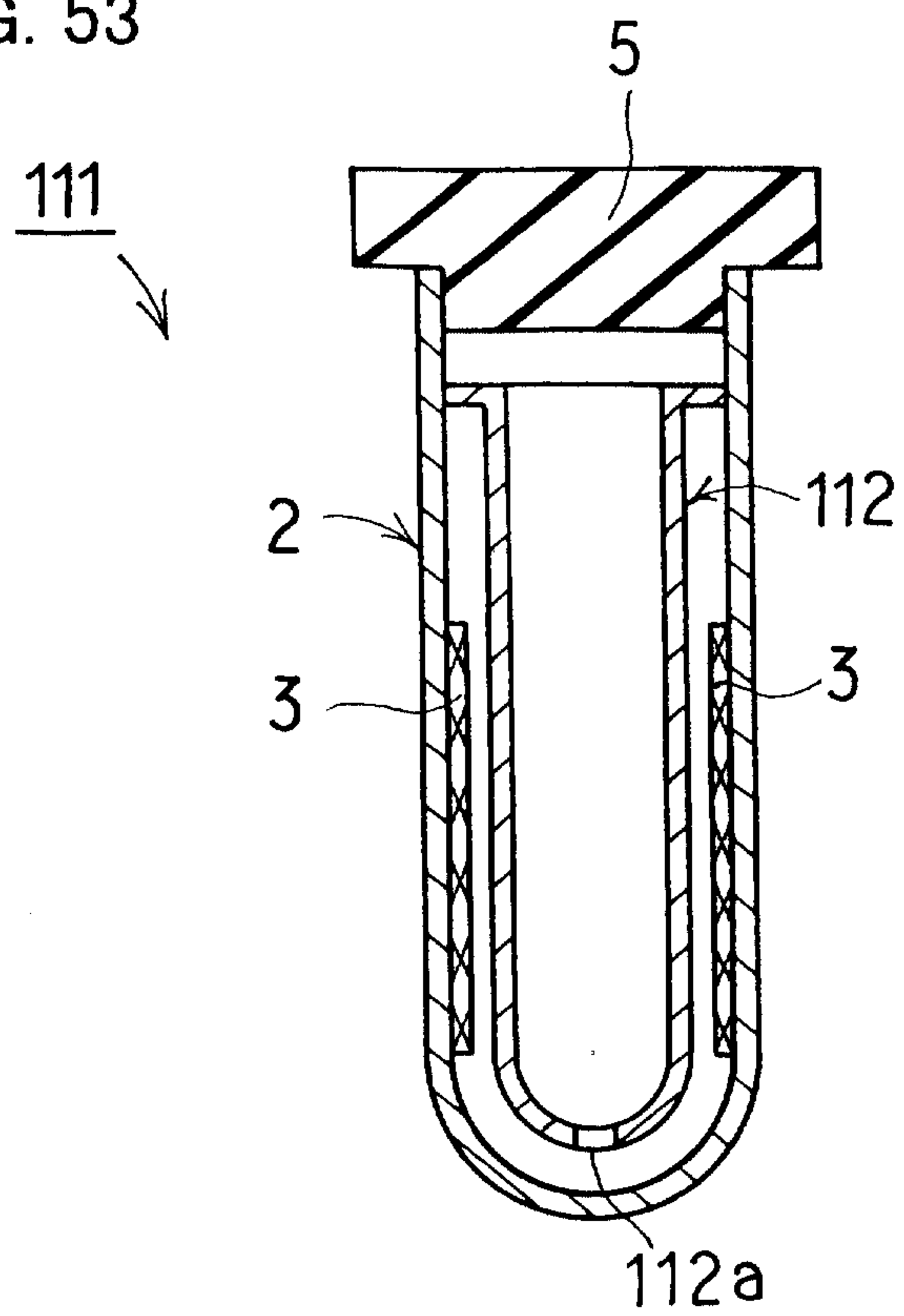


FIG. 54

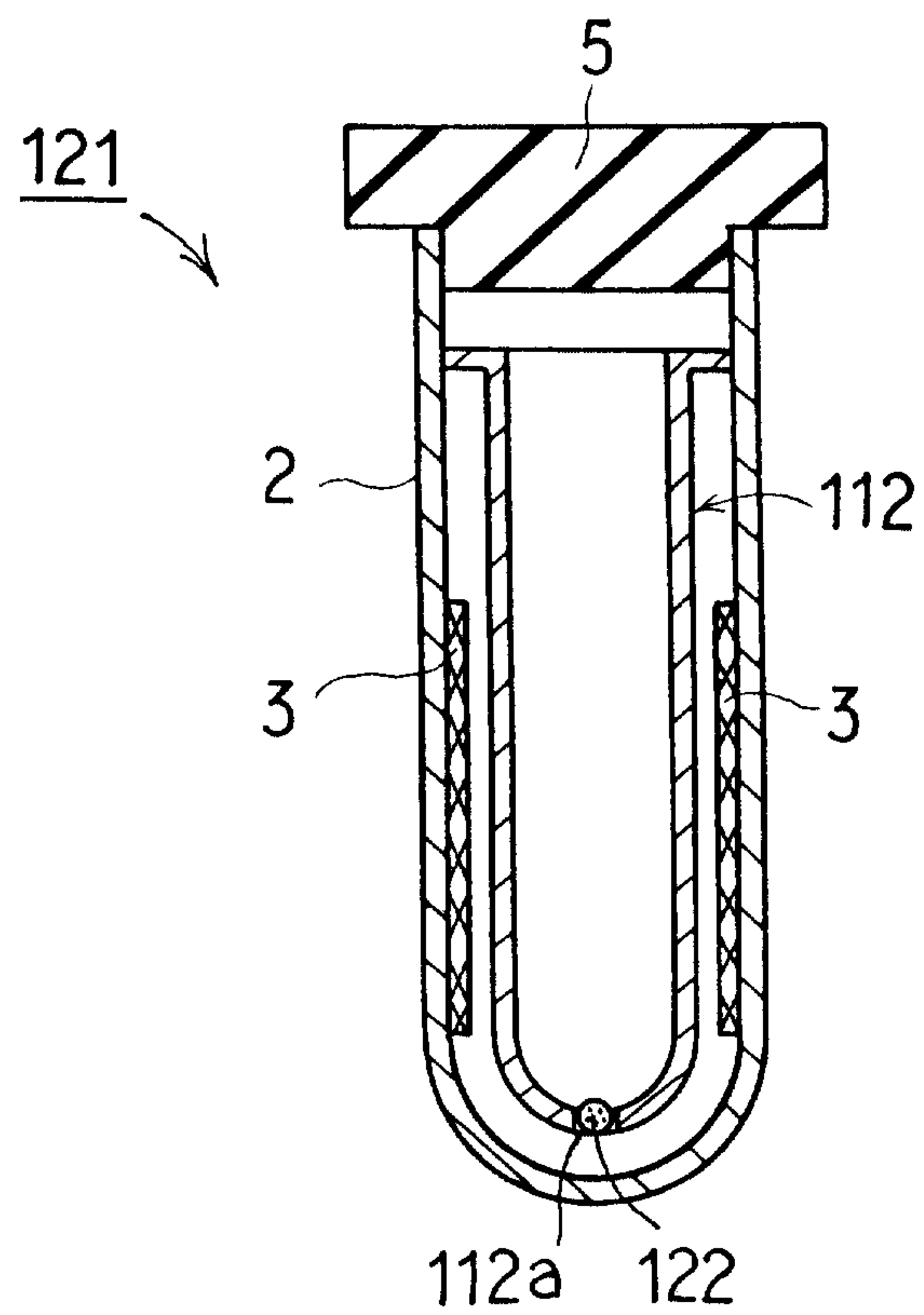


FIG. 55

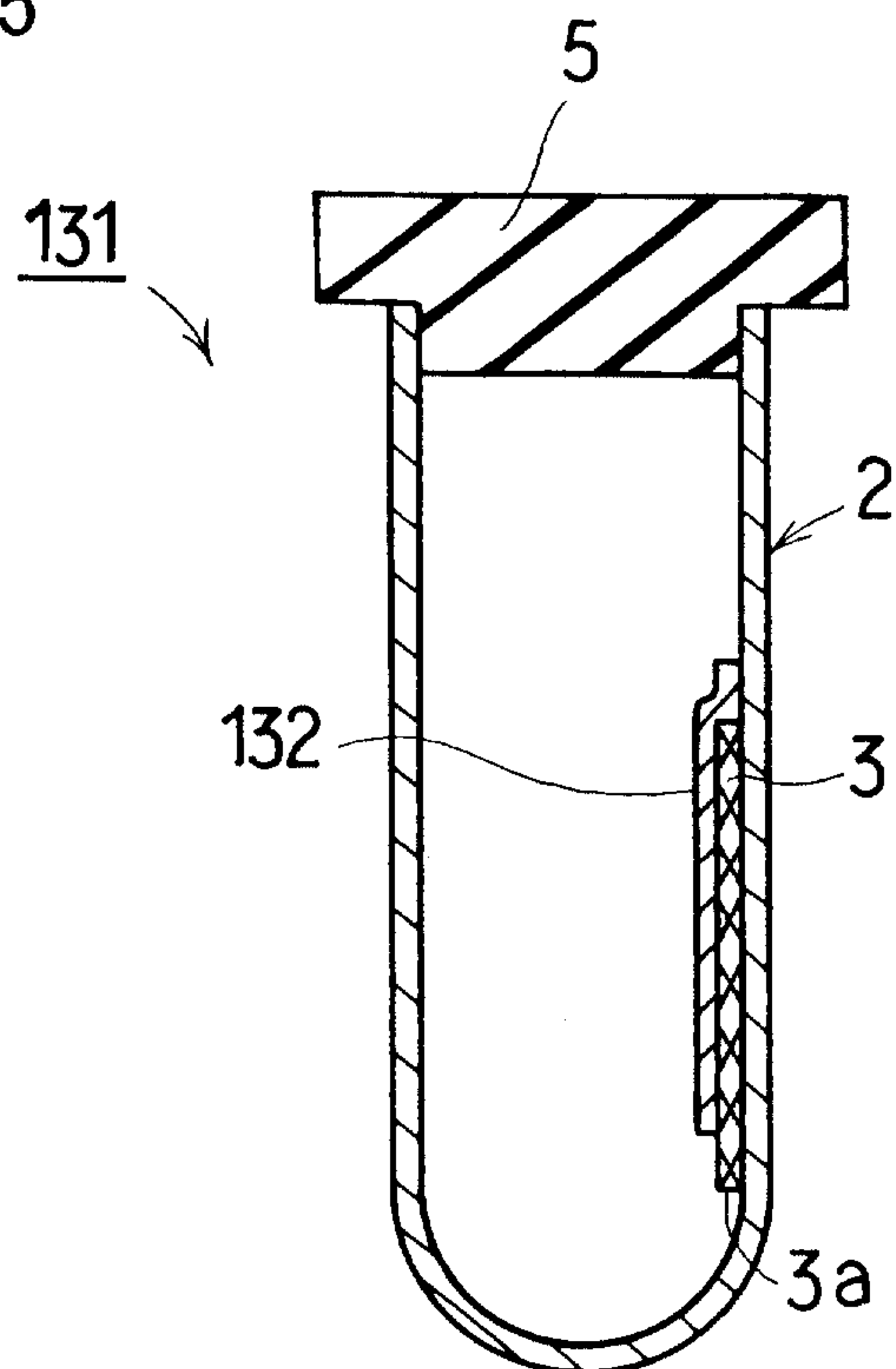


FIG. 56

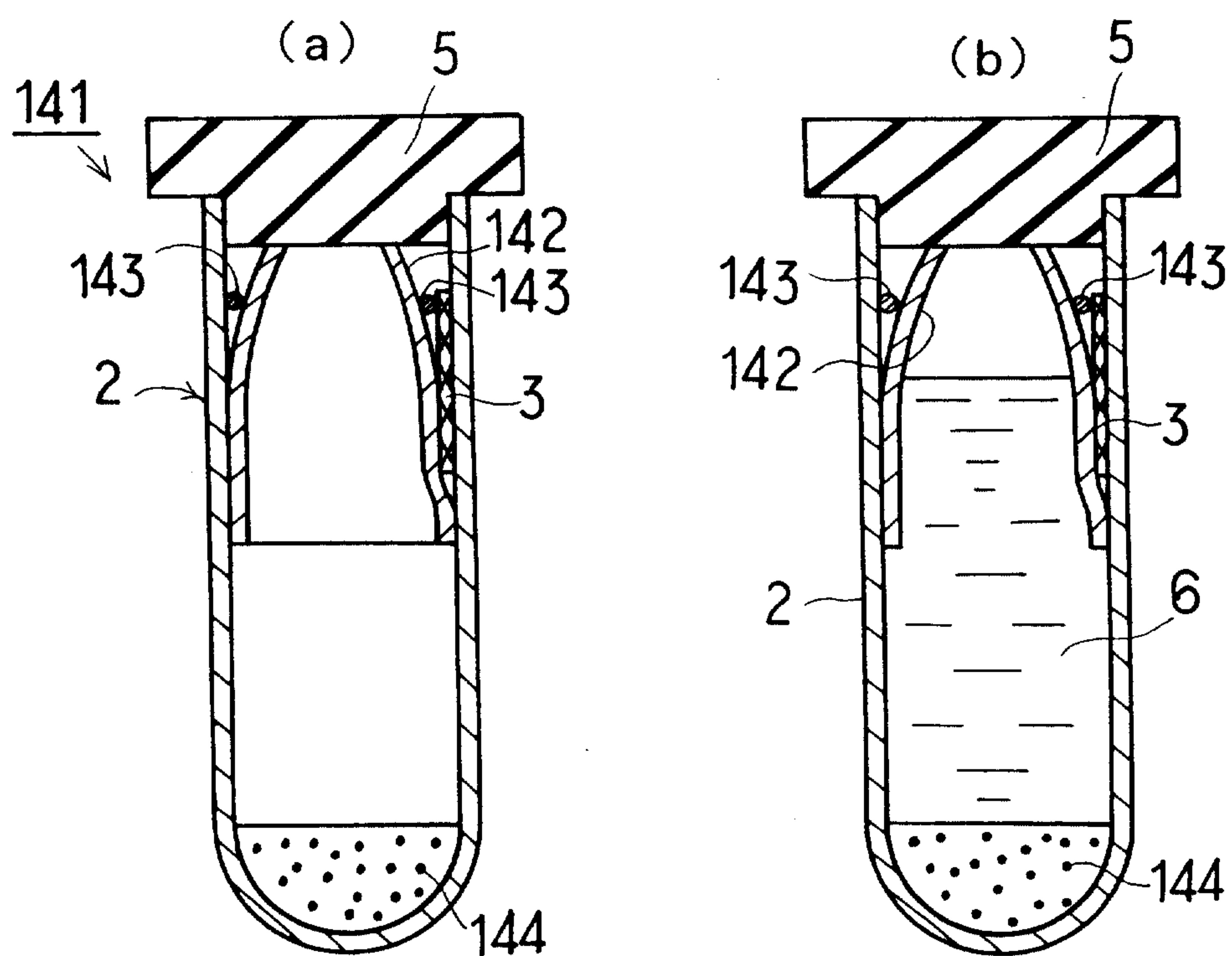


FIG. 57

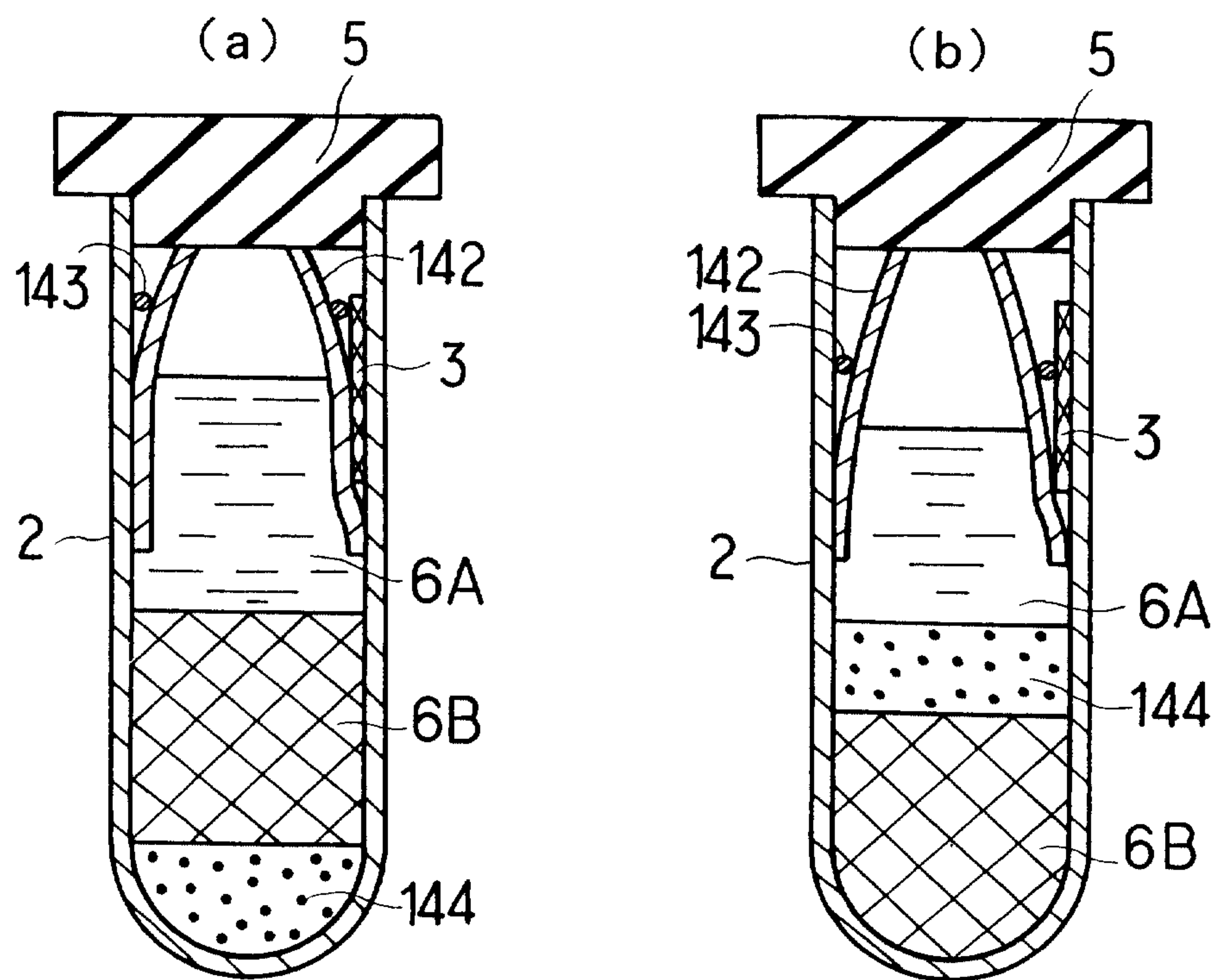


FIG. 58

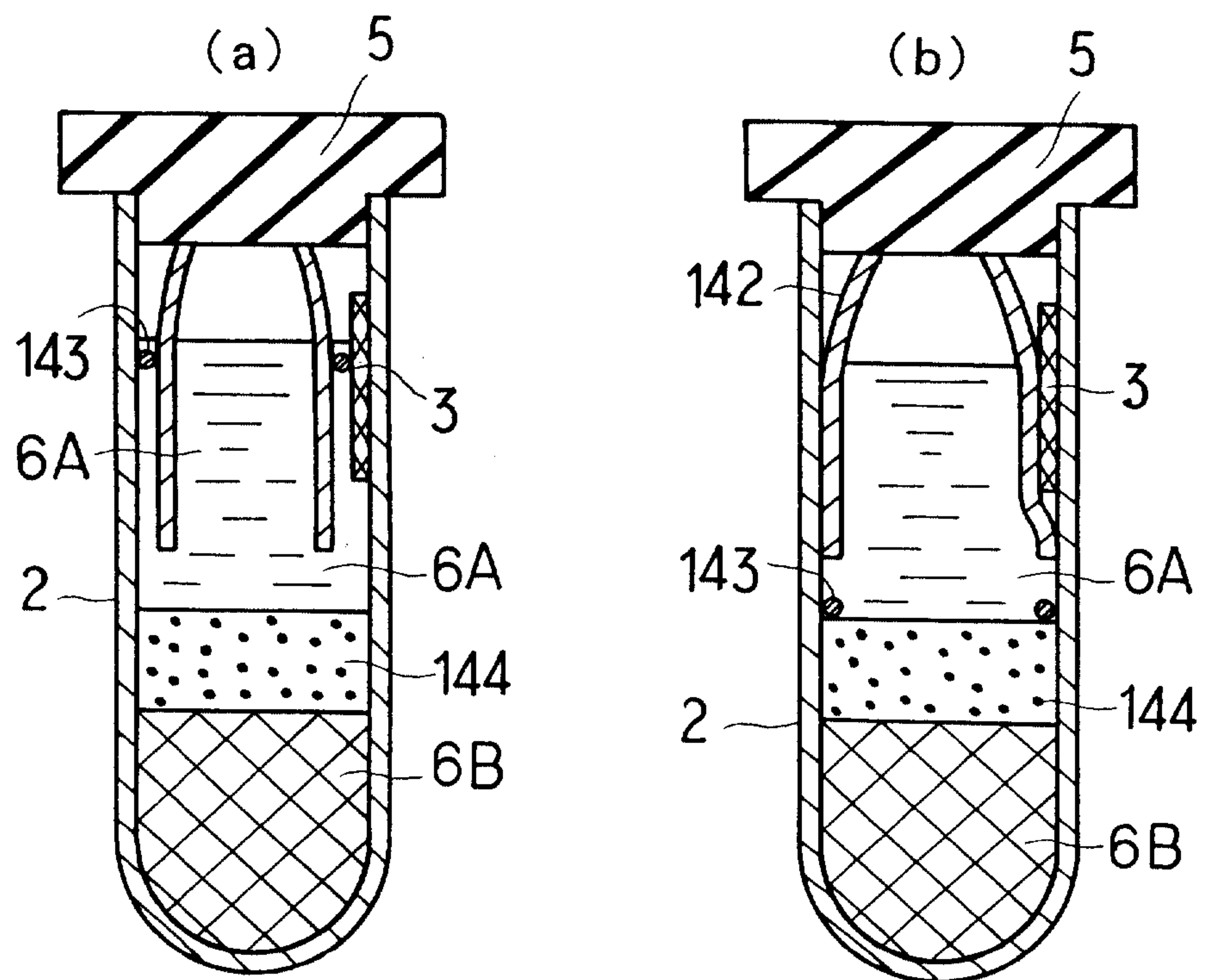


FIG. 59

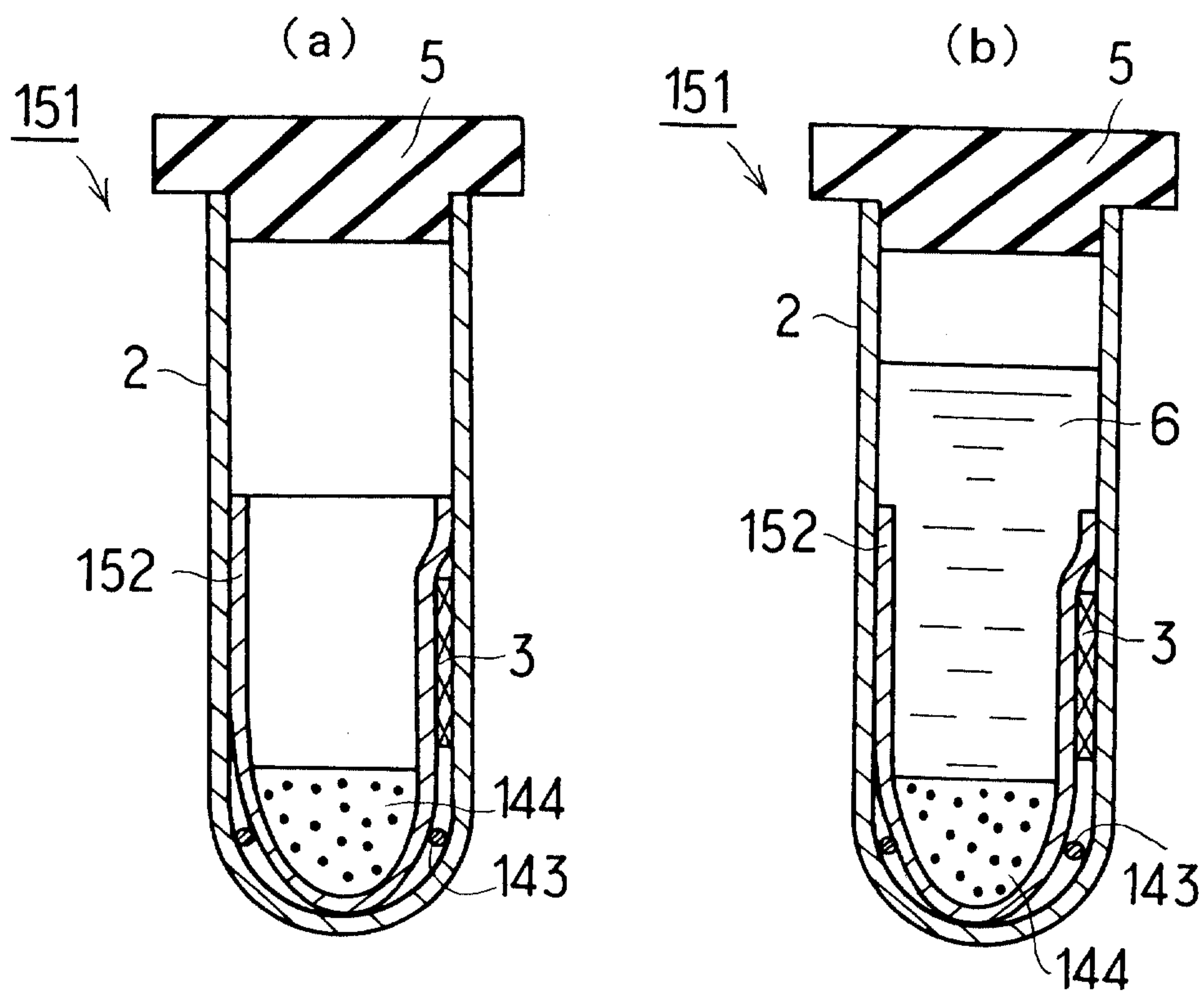


FIG. 60

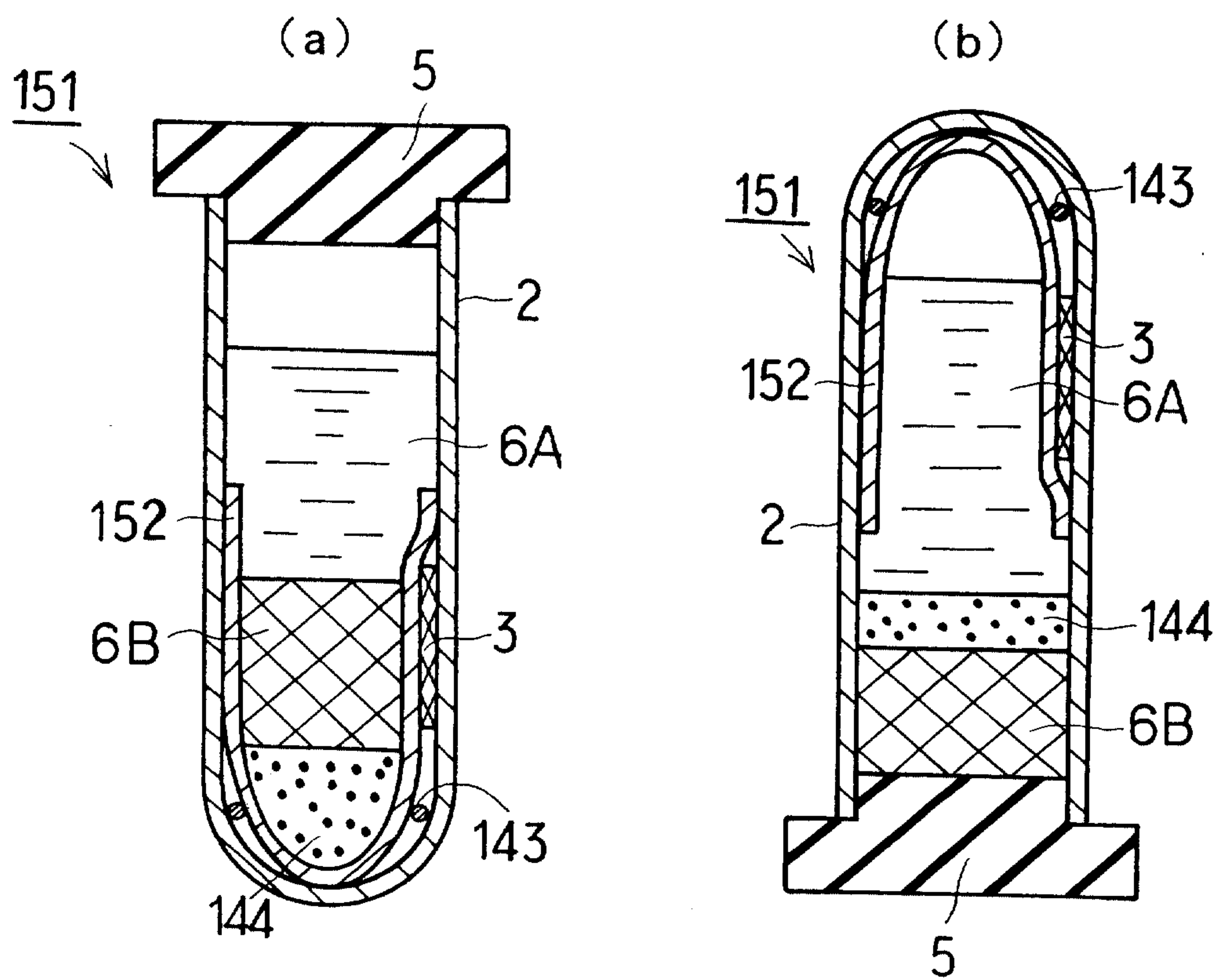


FIG. 61

