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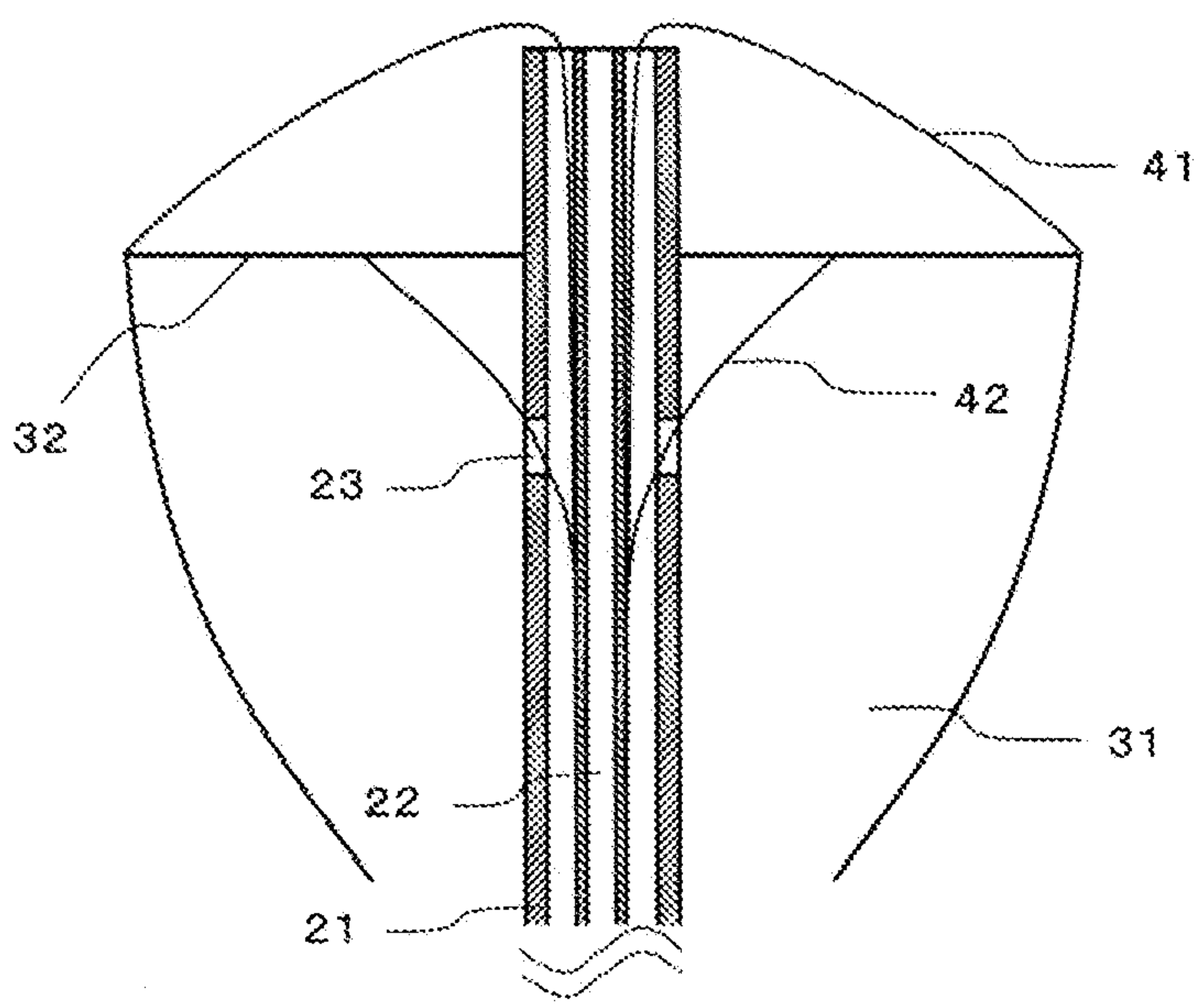
(54) Title: FILTER DEVICE

[図3]



(57) Abrégé/Abstract:
The purpose of the present invention is to provide a filter device capable of reliably capturing an embolus, such as thrombosis or bubbles occurring in intra-blood vessel treatment or the like, and also reliably removing the captured embolus from the body. The present invention provides a filter device provided with: a first tube; a second tube protruding from the first tube; a filter arranged so that a tip side in the longitudinal direction becomes an opening part; a ring fixed to the opening part; a first wire protruding from the tip side in the longitudinal direction of the first tube; and a second wire protruding from a hole of the first tube and fixed to the ring, wherein the opening part can be opened and closed in the shape of an envelope when a base end side in the longitudinal direction is used as a bottom surface, and can be closed by pulling the second tube toward the base end side in the longitudinal direction.

ABSTRACT

An object of the present invention is to provide a filter device capable of reliably capturing emboli, such as thrombi and air bubbles formed due to an endovascular treatment or the like, and reliably removing the captured emboli out of the body. The present invention provides a filter device including: a first tube; a second tube protruding from the first tube; a filter arranged such that the distal end side of the filter in the longitudinal direction forms an opening; a ring fixed to the opening; first wires protruding from the distal end side of the first tube in the longitudinal direction thereof; and second wires protruding from holes in the first tube and fixed to the ring; wherein the opening can be opened and closed in the form of a bag when the proximal end side of the filter in the longitudinal direction is defined as the bottom, and the opening can be closed by pulling the second tube towards the proximal end side in the longitudinal direction.

DESCRIPTION

FILTER DEVICE

TECHNICAL FIELD

[0001]

The present invention relates to a filter device for capturing thrombi and the like.

BACKGROUND ART

[0002]

Atrial fibrillation is one type of cardiac arrhythmias, and is known as a condition in which irregular arterial contractions occurs repeatedly to deteriorate blood circulation, thereby causing discomfort and feeling of fatigue. Accordingly, methods of treating atrial fibrillation by catheter ablation procedures have been widely used, in recent years, in which procedures, myocardial tissues, such as pulmonary veins and the posterior wall of the left atrium in the vicinity of the pulmonary veins, which are primary sites of occurrence of atrial fibrillation, are thermally ablated.

[0003]

However, these procedures have a problem that a thrombus which has been formed due to deterioration of blood circulation, or a thrombus which is formed due to the heat of the ablation procedure at an affected site or on a medical device, may be carried away by the blood flow recovered by the treatment, possibly causing infarction in a peripheral blood vessel.

[0004]

At present, there have been developed filter devices for receiving substances such as released thrombi, plaques and the like, in order to avoid the risk of occurrence of infarction in peripheral blood vessels and the like. As an example of such a filter device, a device for capturing emboli has been reported which can be used in the case of carrying out a surgery or a procedure that may possibly cause the formation of emboli upstream of the blood flow (Patent Document 1). Further, there has also been reported an intravascular blood filter which can be placed in and removed from a blood vessel, in which the opening of the filter being in close contact with the inner wall of an artery in a favorable manner, and which is capable of reliably capturing tissue pieces (Patent Document 2).

PRIOR ART DOCUMENTS

PATENT DOCUMENTS

[0005]

Patent Document 1: JP 5749094 B

Patent Document 2: JP 4067353 B

SUMMARY OF THE INVENTION

PROBLEMS TO BE SOLVED BY THE INVENTION

[0006]

In the case of capturing a thrombus which has been formed due to deterioration of blood circulation or a thrombus which is generated from a thermally ablated portion during the ablation procedure, by a filter, before the thrombus is carried away by the blood flow recovered by the treatment and flows to a peripheral organ, such as brain, it is desired that the filter can be removed out of the body with the opening of the filter securely closed so that the captured embolus can be prevented from being released into the body again.

[0007]

The device for capturing emboli disclosed in Patent Document 1 is configured such that the opening of a filter portion is arranged to face the distal end side of a shaft member so that the blood flow and the opening are opposed to each other, and the filter portion is folded and closed by being stowed inside a microcatheter.

However, since the filter portion does not have a mechanism for closure, there is a possibility that the captured emboli may be released when the filter portion fails to be properly folded upon stowing.

[0008]

Further, the intravascular blood filter disclosed in Patent Document 2 includes: wires for pulling forward which connect a member for opening and closing the filter with a core material; and wires for pulling backward which connect a filter ring with a catheter member. In the intravascular blood filter, the opening of the filter portion is opened and closed by the deformation and restoration of the member for opening and closing the filter, which are achieved by the movement of the core material relative to the catheter member, in the axial direction. However, in the intravascular blood filter, the core material functions as a guide wire, and when the function of the core material as a guide wire for guiding the filter to a target site is used during the procedure, the core material as the guide wire is rotated, and there is a possibility that the wires for pulling may be entangled with the core material or the catheter member. In this case, the opening of the filter portion may not be sufficiently controlled, possibly resulting in a failure to capture the emboli generated during the procedure.

[0009]

Therefore, an object of the present invention is to provide a filter device in which the opening and closing of the opening of the filter portion can be sufficiently controlled, so as to allow for capturing emboli and for removing the captured emboli out of the body without releasing them from the filter portion.

MEANS FOR SOLVING THE PROBLEMS

[0010]

As the result of intensive studies to solve the above mentioned problems, the present inventors have arrived at the following inventions (1) to (4).

(1) A filter device including:

a first tube having holes on the side surface thereof;

a second tube inserted through the first tube and protruding from the proximal end side of the first tube in the longitudinal direction thereof;

a filter arranged such that the filter has a closed end portion on the proximal end side in the longitudinal direction of the first tube, and such that the distal end side of the filter in the longitudinal direction forms an opening;

a ring fixed to the opening and having elasticity or shape memory property;

first wires inserted between the first tube and the second tube, wherein the proximal ends of the first wires are fixed to the second tube, and the distal ends of the first wires protrude from the distal end side of the first tube in the longitudinal direction thereof and are fixed to portions of the ring; and

second wires inserted between the first tube and the second tube, wherein the proximal ends of the second wires are fixed to the second tube, and the distal ends of the second wires protrude from the holes and are fixed to portions of the ring;

wherein the opening can be opened and closed in the form of a bag when the proximal end side of the filter in the longitudinal direction is defined as the bottom, and the opening can be closed by pulling the second tube towards the proximal end side in the longitudinal direction.

(2) The filter device according to (1), wherein the holes are arranged so as to form equal angles relative to the central axis of the first tube, and arranged on the same circumference.

(3) The filter device according to (1) or (2),

wherein the ring has a cylindrical shape, and

wherein the fixed positions of the first wires to the ring, and the fixed positions of the second wires to the ring, are arranged alternately relative to the central axis of the first tube.

(4) The filter device according to (1) or (2),

wherein the ring includes a plurality of mountains facing the distal end side in the longitudinal direction, and a plurality of valleys facing the proximal end side in the longitudinal direction, which mountains and valleys are formed alternately,

wherein the fixed positions of the first wires to the ring are provided at the apices of the mountains, and

wherein the fixed positions of the second wires to the ring are provided at the bottoms of the valleys.

EFFECT OF THE INVENTION

[0011]

According to the present invention, it is possible to reliably and easily close the opening of the filter, since the operation of moving the second tube relative to the first tube allows the first wires and the second wires to open and close the opening of the filter. As a result, it becomes possible to remove the captured emboli out of the body without allowing them to flow out of the filter portion.

[0012]

Further, a guide wire can be inserted through the lumen of the second tube, and the filter device can be delivered along the guide wire placed in a blood vessel in advance, and thus there is no need to rotate the device.

[0013]

According to the above described invention, the ring fixed to the opening is made of a wire having elasticity or shape memory property, so that the ring can be expanded in the direction vertical to the longitudinal direction. Therefore, the filter opening can be self-expanded outward in the direction vertical to the longitudinal direction, thereby allowing for an improved adhesion to the inner wall of a blood vessel, and enabling to reliably capture emboli, such as thrombi and air bubbles formed due to an endovascular treatment or the like.

[0014]

According to the above described invention, the ring has a cylindrical shape, and the fixed positions of the first wires to the ring, and the fixed positions of the second wires to the ring, are arranged alternately relative to the central axis of the first tube. Therefore, the filter can be deformed in a favorable manner, so as to ensure a more reliable closure of the opening.

[0015]

Further, when the wires are pulled to the proximal end side, the ring is deformed in the form of waves, due to the difference in pulling capacity between the first wires and the second wires, and thus, the closure of the opening can further be improved.

[0016]

According to the above described invention, the ring has a shape which includes a plurality of mountains facing the distal end side in the longitudinal direction, and a plurality of valleys facing the proximal end side in the longitudinal direction, which mountains and valleys are formed alternately. Further, the fixed positions of the first wires to the ring are provided at the apices of the mountains, and the fixed positions of the second wires to the ring are provided at the bottoms of the valleys. Therefore, the filter can be deformed in a favorable manner, so as to ensure a more reliable closure of the opening.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017]

FIG. 1 is an explanatory diagram showing a first embodiment of the filter device according to the present invention.

FIG. 2 is an explanatory diagram showing the first tube included in the filter device shown in FIG. 1.

FIG. 3 is an enlarged sectional view of the filter device shown in FIG. 1, when the filter portion is opened.

FIG. 4 is an enlarged view of the filter device shown in FIG. 1, seen from the distal end side of the device.

FIG. 5 is an enlarged sectional view of the filter device shown in FIG. 1, when the filter portion is closed.

FIG. 6 is an explanatory diagram showing the process of closing the opening of the filter device shown in FIG. 1.

FIG. 7 is an explanatory diagram showing a second embodiment of the filter device according to the present invention.

FIG. 8 is an enlarged sectional view of the filter device shown in FIG. 7, when the filter portion is opened.

FIG. 9 is an enlarged sectional view of the filter device shown in FIG. 7, when the filter portion is closed.

FIG. 10 is an explanatory diagram showing the process of closing the opening of the filter device shown in FIG. 7.

FIG. 11 is an explanatory diagram showing the filter device of Comparative Example 1.

FIG. 12 is an explanatory diagram showing the intravascular blood filter of Comparative Example 2.

FIG. 13 is an explanatory diagram showing an experimental system for carrying out a missing rate experiment using simulated embolic particles.

MODE FOR CARRYING OUT THE INVENTION

[0018]

Specific embodiments of the present invention will now be described with reference to the drawings. However, the present invention is in no way limited to these embodiments. The proportions of the drawings do not necessarily match those of the description.

[0019]

< First Embodiment >

FIG. 1 is a schematic diagram of a filter device 1 according to the first embodiment. The filter device 1 according to the present invention is used, for example, when carrying out a catheter ablation procedure for treating atrial fibrillation, as a device for preventing a situation where a thrombus which has been formed due to deterioration of blood circulation or a thrombus which is generated from a thermally ablated portion is carried away by the blood flow recovered by the treatment, and flows into a peripheral blood vessel, to cause the occurrence of infarction. The filter device 1 according to the first embodiment includes: a body portion 2 for allowing the filter portion to be moved to a target site within a blood vessel; a filter portion 3 for capturing thrombi; and first wires 41 and second wires 42 for opening and closing the opening of the filter portion 3.

[0020]

The body portion 2 includes: a first tube 21; and a second tube 22 inserted through the lumen of the first tube 21. The second tube 22 is configured such that the proximal end of the second tube 22 protrudes from the proximal end side of the first tube 21, and such that the second tube 22 can be moved relative to the first tube 21. Further, a guide wire can be inserted through the lumen of the second tube 22. By this arrangement, the body portion 2 can be moved along the guide wire placed in a blood vessel in advance, thereby enabling to deliver the filter device 1 to a target affected site.

[0021]

The first tube 21 includes holes 23 through which the second wires 42 to be described later can be inserted. The first tube 21 preferably includes a plurality of the holes 23 in a number corresponding to the number of the second wires 42. Further, in a case in which the first tube 21 includes a plurality of the holes 23, the holes 23 are arranged so as to form substantially equal angles relative to the central axis of the first tube 21, and arranged in the same circumferential direction. The first tube 21 in the first embodiment includes, as shown in FIG. 2, four holes 23 arranged in the same circumferential direction, and the four holes 23 are arranged at such intervals that respective two adjacent holes 23 form 90 degrees relative to the central axis of the first tube 21. Further, a connector 24 is fixed to the proximal end side of the first tube 21 in the longitudinal direction.

[0022]

As the materials of the first tube 21 and the second tube 22, any material having flexibility may be used. Examples thereof include: polyolefins such as polyurethane, polyamide, silicone, polypropylene and polyethylene; as well as thermoplastic resins such as polyether ketone resins (PEEK), fluorine resins, ethylene-tetrafluoroethylene copolymers (ETFE) and polytetrafluoroethylene resins (PTFE) and polyimide resins.

[0023]

In cases where a resin such as polyamide or polyimide is used as the material of the first tube 21, an easily slidable resin, such as polytetrafluoroethylene may be incorporated into an inner layer, in order to improve the slidability of the second tube 22. Further, it is also possible to incorporate a braided layer formed using a metal wire such as a stainless steel wire, or a resin such as polyamide, in order to ensure the rigidity of the tube.

[0024]

The first tube 21 preferably has a length of from about 700 to 1,250 mm, for example, in the case of inserting the filter device 1 from the femoral artery to be placed in the ascending aorta. Further, the first tube 21 preferably has an outer diameter of from about 1.5 to 3.3 mm, and more preferably from about 1.7 to 3.3 mm.

[0025]

As the first tube 21, a tube formed as an integrated tube may be used, or alternatively, a tube composed of a plurality of tubes may be used.

[0026]

Further, the surface of the first tube 21 is preferably subjected to an antithrombogenic treatment, since thrombi may be adhered to, or formed on, the surface of the tube.

[0027]

The second tube 22 is required to have a length longer than that of the first tube 21, and preferably has a length of from about 800 to 1,350 mm. Further, the second tube 22 is required to have an inner diameter through which a guide wire commonly used in a catheter treatment for circulatory system can be inserted. The second tube 22 preferably has, for example, an inner diameter of from about 0.40 to 1.00 mm, so that a guide wire having a diameter of from 0.014 to 0.035 inches can be inserted therethrough.

[0028]

To facilitate the insertion of a guide wire into the lumen of the second tube 22, it is preferred that the second tube 22 be configured such that the distal end thereof coincides with, or protrudes from, the distal end of the first tube 21, when the filter portion 3 is opened. By the above described configuration, it becomes possible to easily insert the guide wire into the lumen of the second tube 22.

[0029]

The connector 24 is fixed to the proximal end side of the first tube 21, as shown in FIG. 1, and includes: a liquid inflow port 241 capable of injecting a physiological saline solution or the like into the lumen of the first tube 21; and a hemostasis valve 242 which prevents the leaking of blood when the second tube 22 is operated and not operated. It is more preferred that the hemostasis valve 242 be configured such that the valve can be opened and closed by a rotary motion or the like. By the above described configuration, the second tube 22 can be operated when the hemostasis valve 242 is opened, and the second tube 22 can be fixed when the hemostasis valve 242 is closed.

[0030]

The filter portion 3 includes: a filter 31 in the form of a bag; and a ring 32 which has a cylindrical shape, which is fixed to the opening of the filter 31, and which contributes to the opening and closing of the opening. As shown in FIG. 1, the filter 31 in the first embodiment is in the form of a bag, and configured such that the bottom of the bag, which is located at the proximal end side in the longitudinal direction of the first tube, serves as the closed end portion, and the opening of the bag, which is located at the distal end side in the longitudinal direction, serves as the opening.

[0031]

The filter 31 is disposed at the distal end side in the longitudinal direction of the filter device 1. Further, in the filter device 1 according to the first embodiment, the closed end portion of the filter 31 is fixed to the first tube 21, and the entire shape of the filter device 1 is the shape of an umbrella opened upside down. In the case of placing the filter device 1 in the ascending aorta, for example, the opening of the filter portion 3 preferably has a diameter of from about 25 to 40 mm.

[0032]

As another embodiment different from the first embodiment, the filter device may include a third tube arranged so as to be movable on the first tube 21. The third tube is configured to have an inner diameter larger than that of the first tube, and a length shorter than that of the first tube, so that the third tube can be moved relative to the first tube 21. In cases where the filter device includes the third tube, the filter 31 may be fixed to the third tube. In this case, the length of the filter 31 in the longitudinal direction can be changed, by moving the third tube on the first tube

21. Further, the third tube preferably has such an inner diameter that the gap between the first tube 21 and the third tube is 500 μm or less, so that the captured emboli can be prevented from being released.

[0033]

The filter 31 in the first embodiment is prepared by forming a polymer in the form of a sheet, forming a plurality of pores in the sheet, and then forming the sheet in the form of a bag. However, in order to increase the aperture ratio of the filter, and to ensure a sufficient passage rate of blood, the filter 31 may also be prepared by forming fibers of a polymer or a metal in the form of a mesh, and forming the mesh in the form of a bag.

[0034]

Examples of the material of the filter 31 include: polymers such as polyester, polyurethane and polytetrafluoroethylene; and superelastic metals, such as nickel alloys.

[0035]

The filter 31 may have pores of any size, as long as plaques and the like can be captured while ensuring the blood flow. In the case of preparing the filter 31 by forming pores in a sheet, the diameter of the pores is preferably from 30 to 500 μm, and in the case of preparing the filter 31 using a mesh, one side of an aperture of the mesh is preferably from 30 to 500 μm. Further, the surface of the filter may be subjected to an antithrombogenic treatment.

[0036]

The ring 32 may be made of any material as long as it is a flexible wire having elasticity or shape memory property, which allows the diameter of the ring 32 to be expanded in the direction vertical to the longitudinal direction, and allows the ring to be folded. However, it is appropriate to use a superelastic metal, which can be deformed into various shapes, and can still be restored to the original ring shape.

Therefore, the ring is preferably made of a shape memory polymer or a shape memory alloy, and more preferably made of a nickel alloy.

[0037]

Further, it is desired that the ring 32 have X-ray contrast property, in order to confirm the placement of the filter device in a blood vessel. To impart X-ray contrast property to the ring, an X-ray contrast material may be incorporated into a portion or the entirety of the ring 32. Examples of the X-ray contrast material which can be used include gold, platinum, tungsten, and palladium alloys.

[0038]

In the filter device 1 according to the first embodiment, the ring 32 has a cylindrical shape, and is fixed to the opening of the filter 31.

[0039]

The first wires 41 in the first embodiment are inserted through the first tube 21. One ends of the first wires 41 are fixed to the second tube 22, and the other ends of the first wires 41 protrude from the distal end side of the first tube 21 in the longitudinal direction thereof and fixed to the ring 32. The second wires 42 consist of two or more pieces of wires inserted through the first tube 21. One ends of the second wires 42 are fixed to the second tube 22, and the other ends of the second wires 42 protrude from the holes 23 of the first tube 21 and fixed to the ring 32.

[0040]

Examples of suitable materials of the wires include: polymers such as polyester, polyurethane and polytetrafluoroethylene; stainless steel wires; and superelastic metals, such as nickel alloys. The first wires and the second wires are required to have such a wire diameter that the opening of the filter portion 3 can be smoothly opened and closed, when the second tube 22 is operated.

[0041]

One ends of the first wires 41 and the second wires 42, in the first embodiment, are attached and fixed to the ring 32, as shown in FIG. 3, and the other ends thereof are fixed on the second tube 22.

[0042]

In order to reliably close the opening of the filter portion 3, the first wires 41 and the second wires 42 are preferably configured such that the fixed positions of the first wires 41 to the ring 32, and the fixed positions of the second wires 42 to the ring 32, are arranged alternately relative to the central axis of the first tube. Further, it is preferred that these fixed positions be arranged such that respective two adjacent fixed positions form equal angles relative to the central axis of the ring 32. As shown in FIG. 4, the filter device 1 includes four pieces of the first wires 41 and four pieces of the second wires 42, and the first wires 41 and the second wires 42 are fixed to the ring 32 alternately, at such intervals that respective two adjacent wires form 45 degrees relative to the central axis.

[0043]

Further, the filter portion 3 is configured such that the opening of the filter portion 3 can be closed by pulling the second tube 42 towards the proximal end side in the longitudinal direction. When the second tube 22 is pulled towards the proximal end side, in the filter device 1, it is preferred that the fixed portions at which the second wires 42 are in contact with the ring 32 arrive at the holes 23 at the same time as the fixed portions at which the first wires 41 are in contact with the ring 32 arrive at the distal end of the first tube 21. As shown in FIG. 5, the filter device 1 in this Example is configured such that, when the second tube 22 is pulled, the first wires 41 and the second wires 42 fixed on the second tube 22 are pulled, as a result of which the fixed portions at which the first wires 41 are in contact with the ring 32 are brought closer to the distal end of the first tube 21, and at the same time, the fixed portions at which the second wires 42 are in contact with the ring 32 are brought closer to the holes 23, thereby deforming the cylindrical ring 32. In order to achieve the deformation of the ring 32 by a single operation, the first wires 41 and the second wires 42 are fixed on the second tube 22.

[0044]

According to the filter device 1, as shown in FIG. 6, the fixed portions of the first wires 41 and the second wires 42 to the ring 32 are brought closer to the first tube 21, by holding and pulling the second tube 22 towards the proximal end side, and thus, the cylindrical ring 32 is deformed in the form of waves. As a result, the filter 31 is deformed into a shape having a plurality of mountains and valleys so as to conform to the shape of the ring 32, and the ring 32 comes into contact with the first tube 21. In this manner, the opening of the filter portion 3 can be closed.

[0045]

< Second Embodiment >

FIG. 7 is a schematic diagram showing a filter device 10 according to the second embodiment. The filter device 10 in this Example includes: a body portion 2 for allowing the filter portion to be moved to a target site in a blood vessel; a filter portion 3 for capturing thrombi; and first wires 41 and second wires 42 for opening and closing the opening of the filter portion 3.

[0046]

The difference between the filter device 10 of this Example and the filter device 1 described above is that the ring 33 has a shape in which a plurality of mountains facing the distal end side in the longitudinal direction and a plurality of valleys facing the proximal end side in the longitudinal direction are formed alternately. The features other than the above are the same as the filter device 1 described above. The same portions are denoted with the same reference numerals.

[0047]

The body portion 2 includes: a first tube 21; and a second tube 22 inserted through the lumen of the first tube 21. The second tube 22 is configured such that the proximal end of the second tube 22 protrudes from the proximal end side of the first tube 21, and such that the second tube 22 can be moved relative to the first tube 21. Further, a guide wire can be inserted through the lumen of the second tube 22. By this arrangement, the body portion 2 can be moved along the guide wire placed in a blood vessel in advance, thereby enabling to deliver the filter device 10 to a target affected site.

[0048]

The first tube 21 includes holes 23 through which the second wires 42 to be described later can be inserted. The first tube 21 preferably includes a plurality of the holes 23 in a number corresponding to the number of the second wires 42. Further, in a case in which the first tube 21 includes a plurality of the holes 23, the holes 23 are arranged so as to form substantially equal angles relative to the central axis of the first tube 21, and arranged in the same circumferential direction. As shown in FIG. 2, the holes 23 in the second embodiment are formed such that four holes 23 are arranged in the same circumferential direction of the first tube, and the four holes 23 are arranged at such intervals that respective two adjacent holes 23 form 90 degrees relative to the central axis of the first tube 21. Further, a connector 24 is fixed to the proximal end side of the first tube 21 in the longitudinal direction.

[0049]

To facilitate the insertion of a guide wire into the lumen of the second tube 22, it is preferred that the second tube 22 be configured such that the distal end thereof coincides with, or to slightly protrudes from, the distal end of the first tube 21, when the filter portion 3 is opened.

[0050]

The connector 24 in the second embodiment is fixed to the proximal end side of the first tube 21, as shown in FIG. 7, and includes: a liquid inflow port 241 capable of injecting a physiological saline solution or the like into the lumen of the first tube 21; and a hemostasis valve 242 which prevents the leaking of blood when the second tube 22 is operated and not operated. It is more preferred that the hemostasis valve 242 be configured such that the valve can be opened and closed by a rotary motion or the like. By the above described configuration, the second tube 22 can be operated when the hemostasis valve 242 is opened, and the second tube 22 can be fixed when the hemostasis valve 242 is closed.

[0051]

The filter portion 3 includes: a filter 31 in the form of a bag; and a ring 33 which has a shape in which a plurality of mountains facing the distal end side in the longitudinal direction and a plurality of valleys facing the proximal end side in the longitudinal direction are formed alternately, which is fixed to the opening of the filter 31, and which contributes to the opening and closing of the opening. As shown in FIG. 7, the filter 31 in the second embodiments is in the form of a bag, whose opening, when opened, has a shape in which a plurality of mountains facing the distal end side in the longitudinal direction and a plurality of valleys facing the proximal end side in the longitudinal direction are formed alternately. The filter 31 is configured such that the bottom of the bag, which is located at the proximal end side in the longitudinal direction of the first tube, serves as the closed end portion, and the opening of the bag, which is located at the distal end side in the longitudinal direction, serves as the opening. Further, the closed end portion of the filter 31 is fixed to the first tube 21, and the entire shape of the filter device 1 is the shape of an umbrella opened upside down.

[0052]

In the filter device 10 according to the second embodiment, the ring 33, which has a shape in which a plurality of mountains facing the distal end side in the longitudinal direction and a plurality of valleys facing the proximal end side in the longitudinal direction are formed alternately, is fixed to the opening of the filter 31.

Specifically, as shown in FIG. 7, the ring 33 in which four mountains and four valleys are formed is fixed to the filter member 31.

[0053]

The first wires 41 in the second embodiment are inserted through the first tube 21. One ends of the first wires 41 are fixed to the second tube 22, and the other ends of the first wires 41 protrude from the distal end side of the first tube 21 in the longitudinal direction thereof and fixed to the ring 33. The second wires 42 consist of two or more pieces of wires inserted through the first tube 21. One ends of the second wires 42 are fixed to the second tube 22, and the other ends of the second wires 42 protrude from the holes 23 of the first tube 21 and fixed to the ring 33.

[0054]

As shown in FIG. 8, in the filter device 10 according to the second embodiment, one ends of the first wires 41 are attached and fixed to the apices of the mountains of the ring 33, and one ends of the second wires 42 are fixed to the bottoms of the valleys of the ring 33. Further, the other ends of the first wires 41 and the second wires 42 are fixed on the second tube 22.

[0055]

Further, the filter portion 3 is configured such that the opening of the filter portion 3 can be closed by pulling the second tube 42 towards the proximal end side in the longitudinal direction. When the second tube 22 is pulled towards the proximal end side, in the filter device 10, it is preferred that the fixed portions at which the second wires 42 are in contact with the ring 33 arrive at the holes 23 at the same time as the fixed portions at which the first wires 41 are in contact with the ring 33 arrive at the distal end of the first tube 21. As shown in FIG. 9, the filter device 10 is configured such that, when the second tube 22 is pulled, the first wires 41 and the second wires 42 fixed on the second tube 22 are pulled, as a result of which the apices of the mountains of the ring 33 are brought closer to the distal end of the first tube 21, and at the same time, the bottoms of the valleys of the ring 33 are brought closer to the holes 23. This allows for the deformation of the ring 33, which has a shape in which a plurality of mountains facing the distal end side in the longitudinal direction and a plurality of valleys facing the proximal end side in the longitudinal direction are formed alternately. In order to achieve the deformation of the ring 33 by a single operation, the first wires 41 and the second wires 42 are fixed on the second tube 22.

[0056]

According to the filter device 10, as shown in FIG. 10, the ring 33, which has a shape in which a plurality of mountains facing the distal end side in the longitudinal direction and a plurality of valleys facing the proximal end side in the longitudinal direction are formed alternately, is deformed and brought closer to the first tube 21, by holding and pulling the second tube 22 towards the proximal end side. As a result, the filter 31 is deformed so as to conform to the shape of the ring 33, and the ring 33 comes into contact with the first tube 21. In this manner, the opening of the filter portion 3 can be closed.

EXAMPLES

[0057]

Specific Examples of the filter device 10 according to the present invention will now be described, with reference to the drawings.

[0058]

(Example 1)

The filter device 10 according to the present invention shown in FIG. 7 was produced. In Example 1, the first tube 21 was formed by connecting a plurality of tubes into a single tube. Specifically, a polyamide tube having an outer diameter of 1.58 mm, an inner diameter of 1.25 mm and a length of about 30 mm was prepared, and four holes 23 each having a diameter of about 0.5 mm were formed at positions about 24 mm from the distal end side of the tube, in the same circumferential direction, and at such intervals that respective two adjacent holes 23 form 90 degrees relative to the central axis of the tube.

[0059]

A polyimide tube having an inner diameter of 0.6 mm, a thickness of 0.02 mm and a length of 1,200 mm was used as the second tube 22, and inserted through the polyamide tube.

[0060]

The filter 31 was prepared by using a mesh which is formed from polyester fibers having a monofilament diameter of 28 μm, and in which one side of an aperture was 100 μm, and by forming the mesh in the form of a bag. The filter 31 was configured such that the opening thereof, when opened, has a shape in which a plurality of mountains facing the distal end side in the longitudinal direction and a plurality of valleys facing the proximal end side in the longitudinal direction were formed alternately.

[0061]

The ring 33 was prepared using a nickel-titanium alloy wire having a wire diameter of 0.20 mm, and processed such that the ring had a diameter of 32 mm and a length in the longitudinal direction of 20 mm, and that the ring included four mountains and four valleys formed alternately and at regular intervals so that the entire shape of the ring was in the form of waves. Further, the ring 33 was fixed to the filter 31 using polyurethane, and prepared such that the total length of the filter portion 3 was about 55 mm (including the ring 33).

[0062]

Four pieces of nickel-titanium alloy wires, each having a wire diameter of 42 μm, were used as the first wires 41, and one ends of the wires were attached to the apices of the mountains of the ring 33.

[0063]

Further, four pieces of stainless steel wires, each having a wire diameter of 0.15 mm, were used as the second wires 42, and one ends of the wires were attached to the bottoms of the valleys of the ring 33 by solder.

[0064]

The other ends of the first wires 41 and the second wires 42 were fixed on the second tube such that, when the second tube 22 was pulled, the bottoms of the valleys of the ring 33 arrived at the holes 23 at the same time as the apices of the mountains of the ring 33 arrived at the distal end of the first tube 21, as shown in FIG. 9. At this time, the first and second wires were fixed on the second tube 22 at positions about 50 mm from the distal end portion of the second tube 22.

[0065]

Thereafter, a tube which has a three-layer structure composed of an inner layer of polytetrafluoroethylene, an intermediate layer of a stainless steel braid, and an outer layer of polyimide, and which has an outer diameter of 2.0 mm, an inner diameter of 1.6 mm, and a length of about 1,000 mm, was adhered and connected to the proximal end side of the polyamide tube in the longitudinal direction, using an adhesive, and the resultant was used as the first tube 21. Finally, the proximal end side of the filter 31 was fixed to the outer side of the first tube 21 with the adhesive.

[0066]

(Example 2)

As the filter device of Example 2, a filter device 11 was produced in the same manner as in Example 1, except that the filter device was configured such that the length of the ring 33 in the longitudinal direction was 15 mm, the total length of the filter portion 3 was about 50 mm, and the holes 23 were formed at positions about 20 mm from the distal end side of the first tube 21.

[0067]

(Example 3)

As the filter device of Example 3, a filter device 12 was produced in the same manner as in Example 1, except that the filter device was configured such that the length of the ring 33 in the longitudinal direction was 10 mm, the total length of the filter portion 3 was about 45 mm, and the holes 23 were formed at positions about 16 mm from the distal end side of the first tube 21.

[0068]

(Comparative Example 1)

As the filter device of Comparative Example 1, a filter device 13 was produced in the same manner as in Example 1, except that the second tube 22, the holes 23, the first wires 41 and the second wires 42 were not provided, as shown in FIG. 11. In this case, the filter device does not have a mechanism for closing the filter portion, since the first wires 41 and the second wires 42 are absent.

[0069]

(Comparative Example 2)

As the filter device of Comparative Example 2, an intravascular blood filter 5 disclosed in Patent Document 2 was prepared. Specifically, as shown in FIG. 12, the intravascular blood filter 5 includes: a core material 51; a catheter member 52 provided so as to be slidable on the core material 51; a filter 53 whose distal end side forms an opening, and whose proximal end side is fixed to the distal end side of the catheter member 52; a filter ring 54 provided at the opening of the filter member 53 and facilitates the folding and expansion of the filter member 53; two pieces of wires 55 for pulling forward, which connect the filter ring 54 with the distal end side of the core material 51; and two pieces of wires 56 for pulling backward, which connect the member 53 for opening and closing the filter, with the catheter member 52, in the interior of the filter member 53. In the intravascular blood filter 5, it is possible to deform the filter and to close the opening thereof, by moving the core material 51 relative to the catheter member 52.

[0070]

A stainless steel wire having an outer diameter of 0.55 mm and a length of 1,200 mm was used as the core material 51.

[0071]

A polyimide tube having an outer diameter of 1.7 mm, an inner diameter of 1.6 mm and a length of about 1,000 mm was used as the catheter member 52, and the core material 51 was inserted into the lumen of the catheter member 52.

[0072]

The filter 53 was prepared using a mesh which is formed from polyester fibers having a monofilament diameter of 28 µm, and in which one side of an aperture was 100 µm. The proximal end side of the filter 53 was fixed to the distal end side of the catheter member 52, so that the distal end side of the filter 53 forms an opening.

[0073]

The filter ring 54 was prepared using a nickel-titanium alloy wire having a wire diameter of 0.10 mm and processed in the form of a ring having a diameter of 32 mm. Further, the filter ring 54 was fixed to the filter 53 using polyurethane, and prepared such that the total length of the filter portion 53 was about 55 mm.

[0074]

Two pieces of nickel-titanium alloy wires having a wire diameter of 42 µm were used as the wires 55 for pulling forward, and one ends of the wires 55 were fixed to the filter ring 54, and the other ends of the wires 55 were fixed to the core material 51 at positions 10 mm from the distal end thereof.

[0075]

Further, two pieces of nickel-titanium alloy wires having a wire diameter of 42 µm were used as the wires 56 for pulling backward, and one ends of the wires 56 were fixed to the filter ring 54, and the other ends of the wires 56 were fixed to the catheter member 52 at positions 40 mm from the distal end thereof.

[0076]

The wires 55 for pulling forward and the wires 56 for pulling backward were fixed to the filter ring 54, such that the fixed positions of the wires 55 and the wires 56 are arranged alternately, at such intervals that respective two adjacent fixed positions form 90 degrees relative to the central axis of the catheter member 52.

[0077]

(Comparative Experiment for Determining Missing Rate Using Simulated Embolic Particles)

As shown in the schematic diagram of an experiment model for the comparison of missing rate, shown in FIG. 13, a tube 100 having an inner diameter of 30 mm was prepared, and the tube was filled with water. Simulated embolic particles 120 having a particle size of 150 μm were introduced into the mesh portion, and the filter device was set in the tube 100. Thereafter, the filter device was allowed to pass through a sheath introducer 110 having a diameter of a 10 Fr., and then the operation for removing the filter device 10 was carried out. The comparative experiment of the missing rate was carried out by counting the number of the simulated embolic particles collected, and the number of the simulated embolic particles flowed out of the filter device. The term "missing rate" as used herein refers to the ratio of the number of the simulated embolic particles failed to be collected and flowed out of the filter device relative to the number of the simulated embolic particles introduced into the device, shown in percentage. When carrying out the experiment for each of the filtering devices of Examples 1 to 3, the second tube 22 was held and pulled towards the proximal end side, so as to close the opening of the filter portion 3, and to carry out the removal operation. As a result, each of the filtering devices of Examples 1 to 3, in which the opening of the filter portion 3 can be closed, exhibited a missing rate of less than 5%, whereas the filtering device of Comparative Example 1 exhibited a missing rate of about 42%, as shown in Table 1. The above results have revealed that it is desirable to securely close the opening of the filter portion, so that the captured emboli can be prevented from being released into the body again.

[0078]

[Table 1]

	Presence or absence of mechanism for opening and closing filter	Length of ring in longitudinal direction (mm)	Total length of filter portion (mm)	Number of particles introduced (number)	Number of collected particles (number)	Number of missed particles (number)	Missing rate (%)
Example 1	Yes	20	55	595	588	7	1.2
Example 2	Yes	15	50	593	575	18	3.0
Example 3	Yes	10	45	539	520	19	31.5
Comparative Example 1	No	20	55	581	340	241	41.5

[0079]

(Experiment on Torsional Twist Upon Rotation)

In the intravascular blood filter 5 described in Comparative Example 2, the opening of the filter member 53 was closed by holding the core material 51 and allowing the core material 51 to move forward towards the distal end side relative to the catheter member 52. Subsequently, the core material 51 was held and rotated, in a state where the catheter member 52 was fixed. Further, the core material 51 was pulled relative to the catheter member 52, to close the filter portion. As a result, the wires 55 and 56 for pulling were entangled with the core material 51 or the catheter member 52, failing to sufficiently close the filter member 53.

[0080]

In the intravascular blood filter 5 of the Comparative Example 2, the core material functions as a guide wire, and it has been confirmed that, when the function of the core material as a guide wire for guiding the filter to a target site is used during the procedure, the core material as the guide wire is rotated, causing the wires for pulling to be entangled with the core material or the catheter member. In this case, the opening of the filter portion may not be sufficiently controlled, possibly resulting in a failure to capture the emboli generated during the procedure. In contrast, in the filter device 10 described in Example 1, a guide wire can be inserted through the lumen of the second tube, and the device can be delivered along the guide wire placed in a blood vessel in advance, and thus, there is no need to rotate the device, in the first place.

INDUSTRIAL APPLICABILITY

[0081]

The filter device according to the present invention is capable, by being placed in the ascending aorta during an endovascular treatment, such as a catheter ablation procedure for treating atrial fibrillation or a transcutaneous aortic valve replacement procedure, of capturing and collecting emboli generated by the treatment, and thus preventing the occurrence of infarction.

DESCRIPTION OF SYMBOLS

[0082]

1: Filter device

2: Body portion

3: Filter portion

10, 13: Filter device,

5: Intravascular blood filter

21: First tube

22: Second tube

23: Hole

24: Connector

31: Filter member

32, 33: Ring

41: First wire

42: Second wire

51: Sore material

52: Catheter member

53: Filter member

54: Filter ring

55: Wire for pulling forward

56: Wire for pulling backward

100: Tube

110: Sheath introducer

120: Simulated embolic particles

241: Liquid inflow port

242: Hemostasis valve

CLAIMS

1. A filter device comprising:

a first tube having holes on the side surface thereof;

a second tube inserted through said first tube and protruding from the proximal end side of said first tube in the longitudinal direction thereof;

a filter arranged such that said filter has a closed end portion on the proximal end side in the longitudinal direction of said first tube, and such that the distal end side of said filter in said longitudinal direction forms an opening;

a ring fixed to said opening and having elasticity or shape memory property;

first wires inserted between said first tube and said second tube, wherein the proximal ends of said first wires are fixed to said second tube, and the distal ends of said first wires protrude from the distal end side of said first tube in the longitudinal direction thereof and are fixed to portions of said ring; and

second wires inserted between said first tube and said second tube, wherein the proximal ends of said second wires are fixed to said second tube, and the distal ends of said second wires protrude from said holes and are fixed to portions of said ring;

wherein said opening can be opened and closed in the form of a bag when the proximal end side of said filter in the longitudinal direction is defined as the bottom, and said opening can be closed by pulling said second tube towards the proximal end side in the longitudinal direction.

2. The filter device according to claim 1, wherein said holes are arranged so as to form equal angles relative to the central axis of said first tube, and arranged on the same circumference.

3. The filter device according to claim 1 or 2,

wherein said ring has a cylindrical shape, and

wherein the fixed positions of said first wires to said ring, and the fixed positions of said second wires to said ring, are arranged alternately relative to the central axis of said first tube.

4. The filter device according to claim 1 or 2,

wherein said ring includes a plurality of mountains facing the distal end side in said longitudinal direction, and a plurality of valleys facing the proximal end side in said longitudinal direction, which mountains and valleys are formed alternately,

wherein the fixed positions of said first wires to said ring are provided at the apices of said mountains, and

wherein the fixed positions of said second wires to said ring are provided at the bottoms of said valleys.

Fig. 1

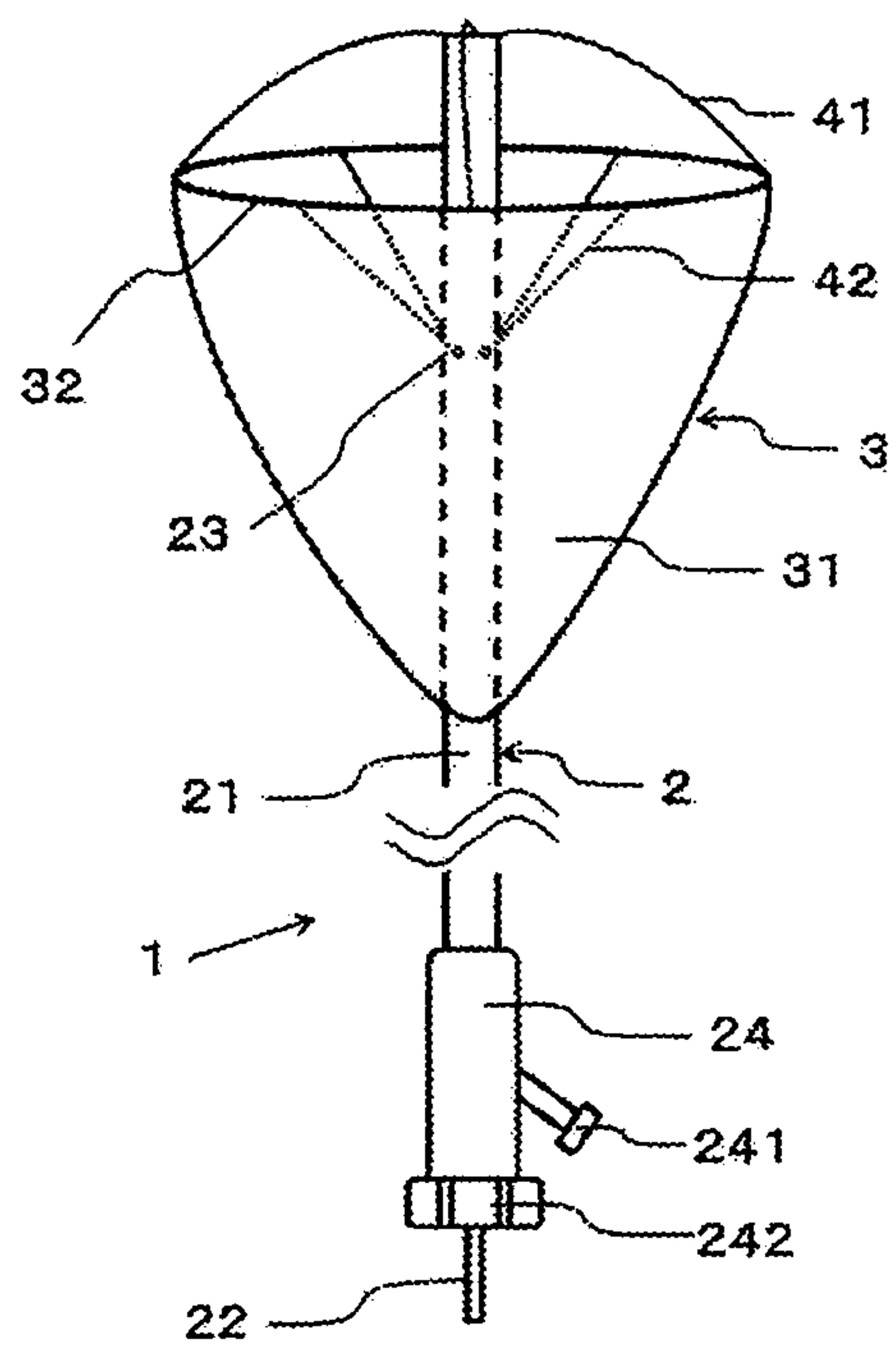


Fig. 2

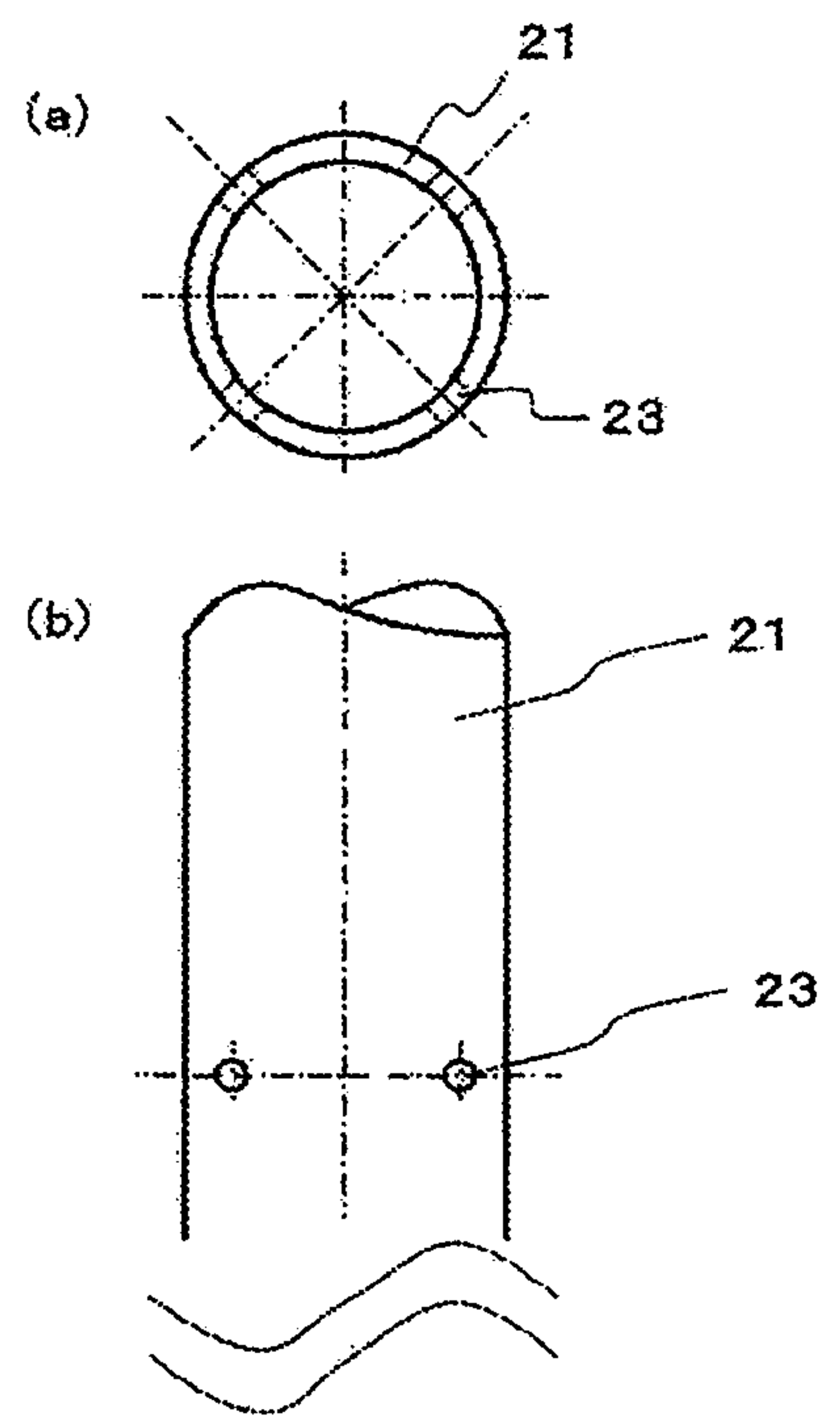


Fig. 3

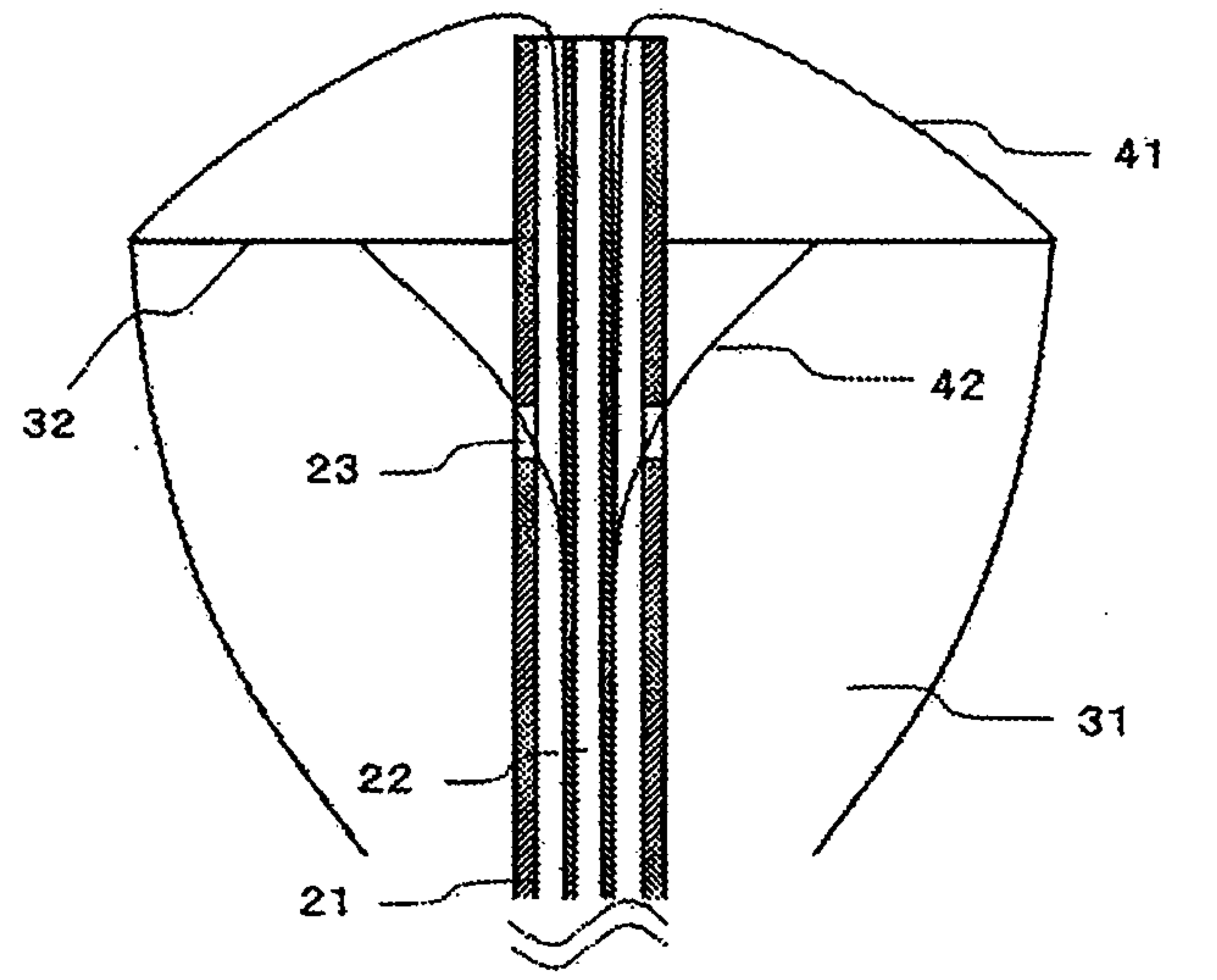


Fig. 4

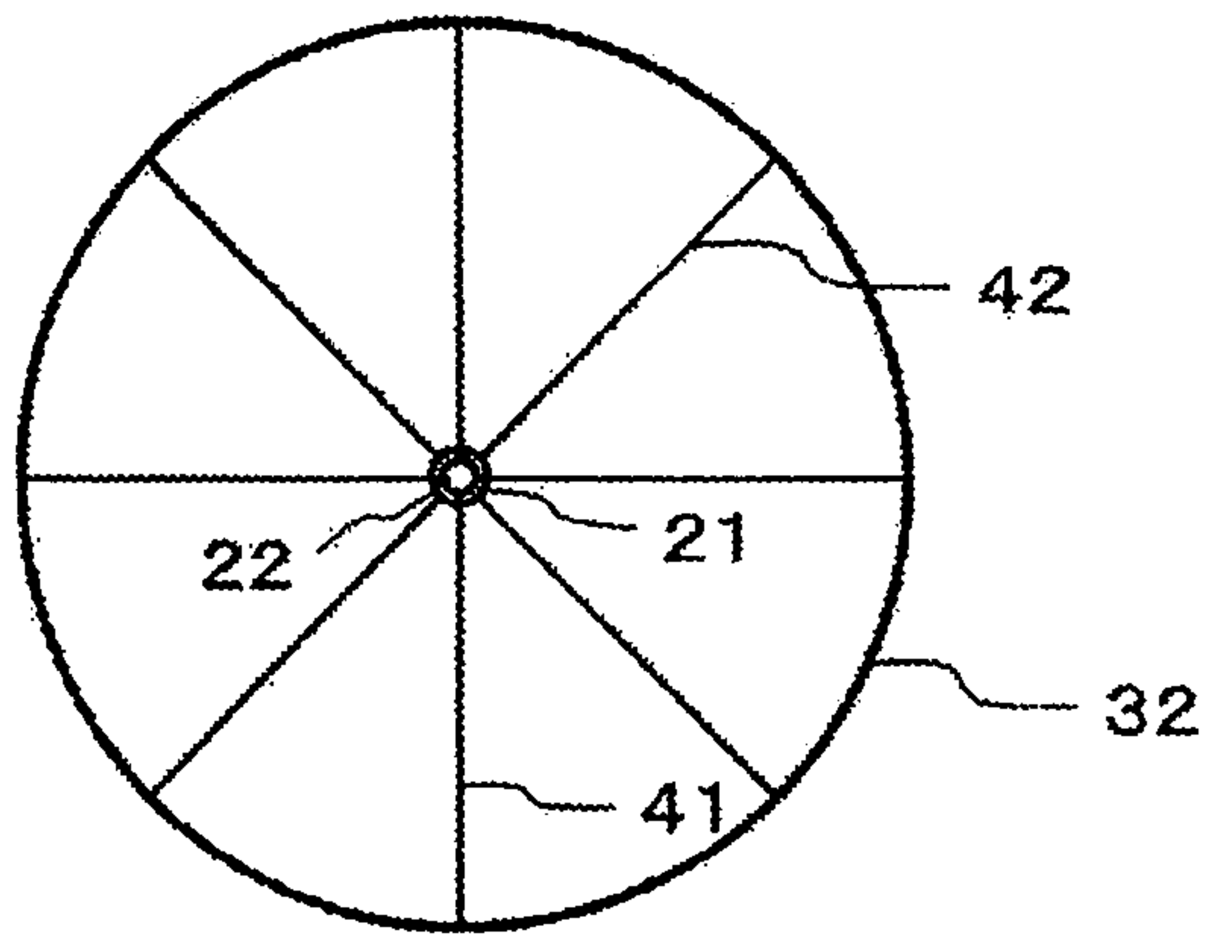


Fig. 5

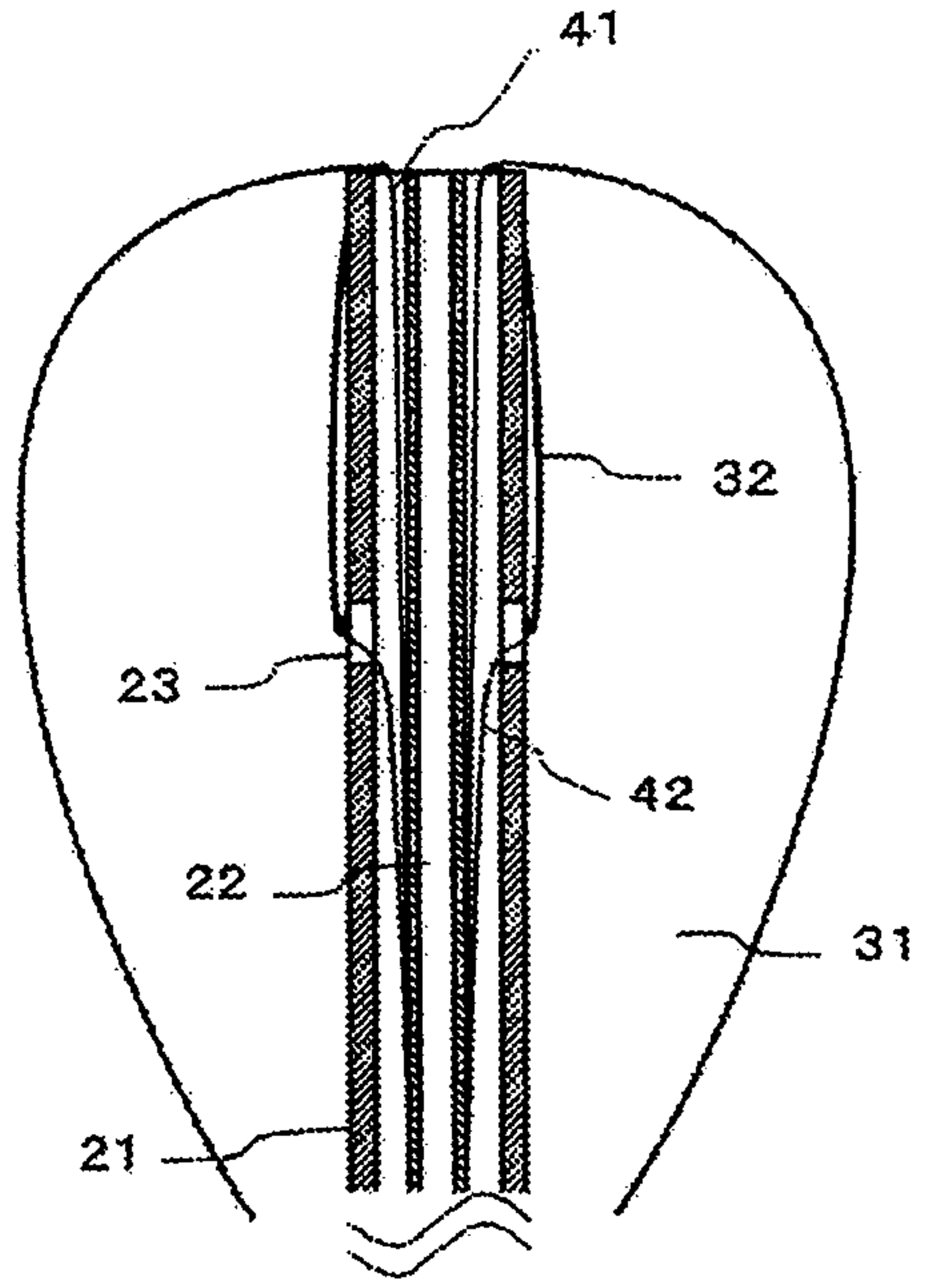


Fig. 6

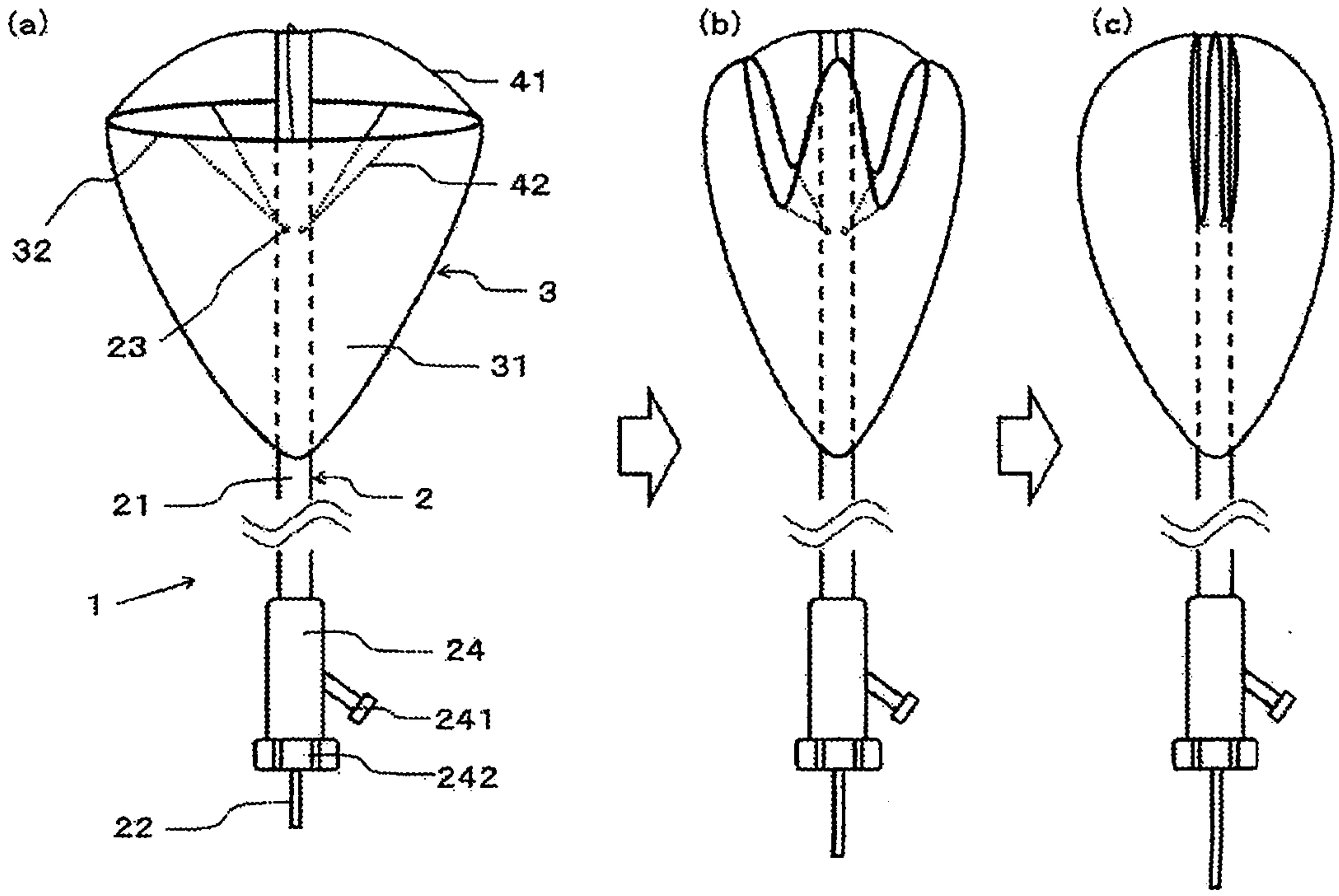


Fig. 7

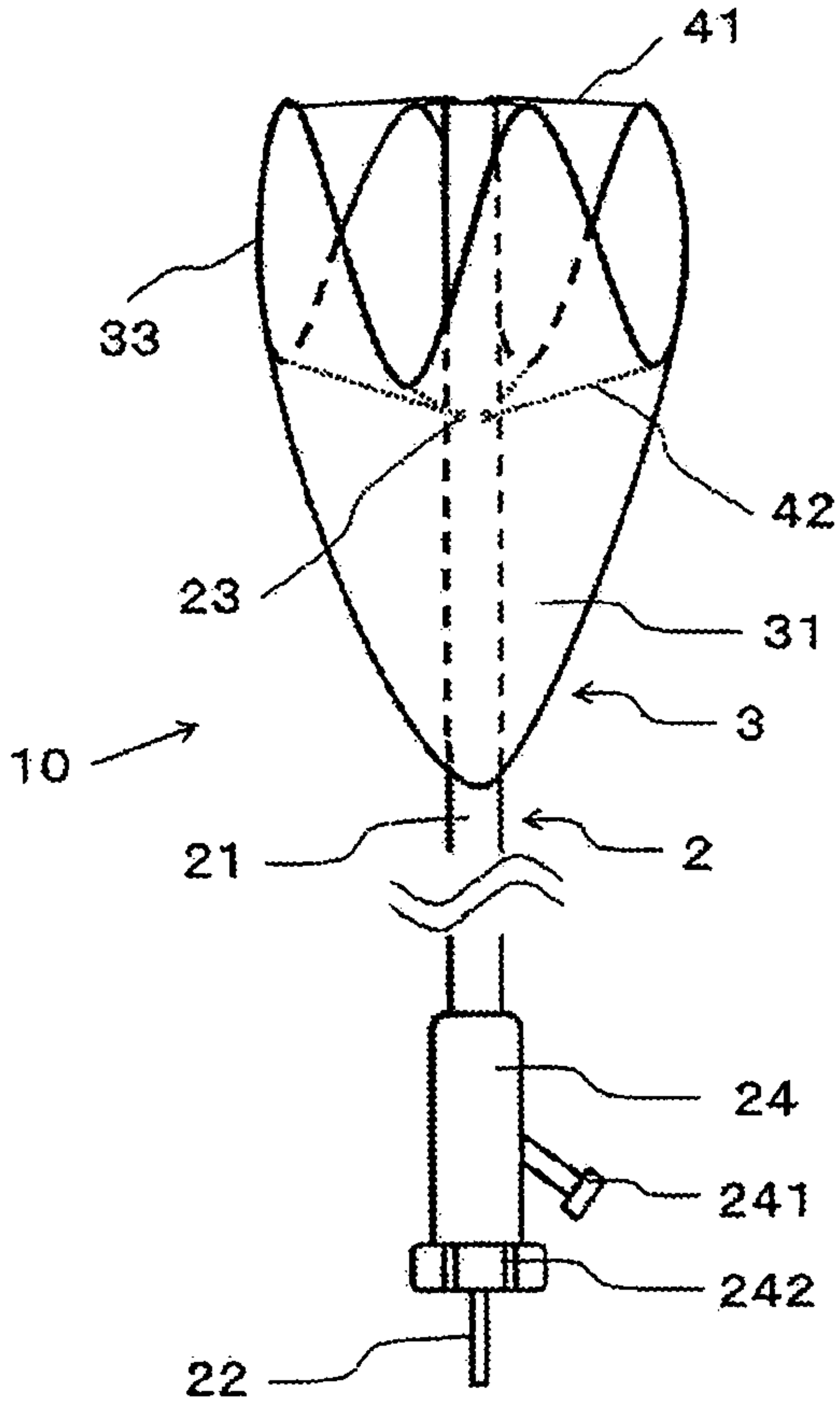


Fig. 8

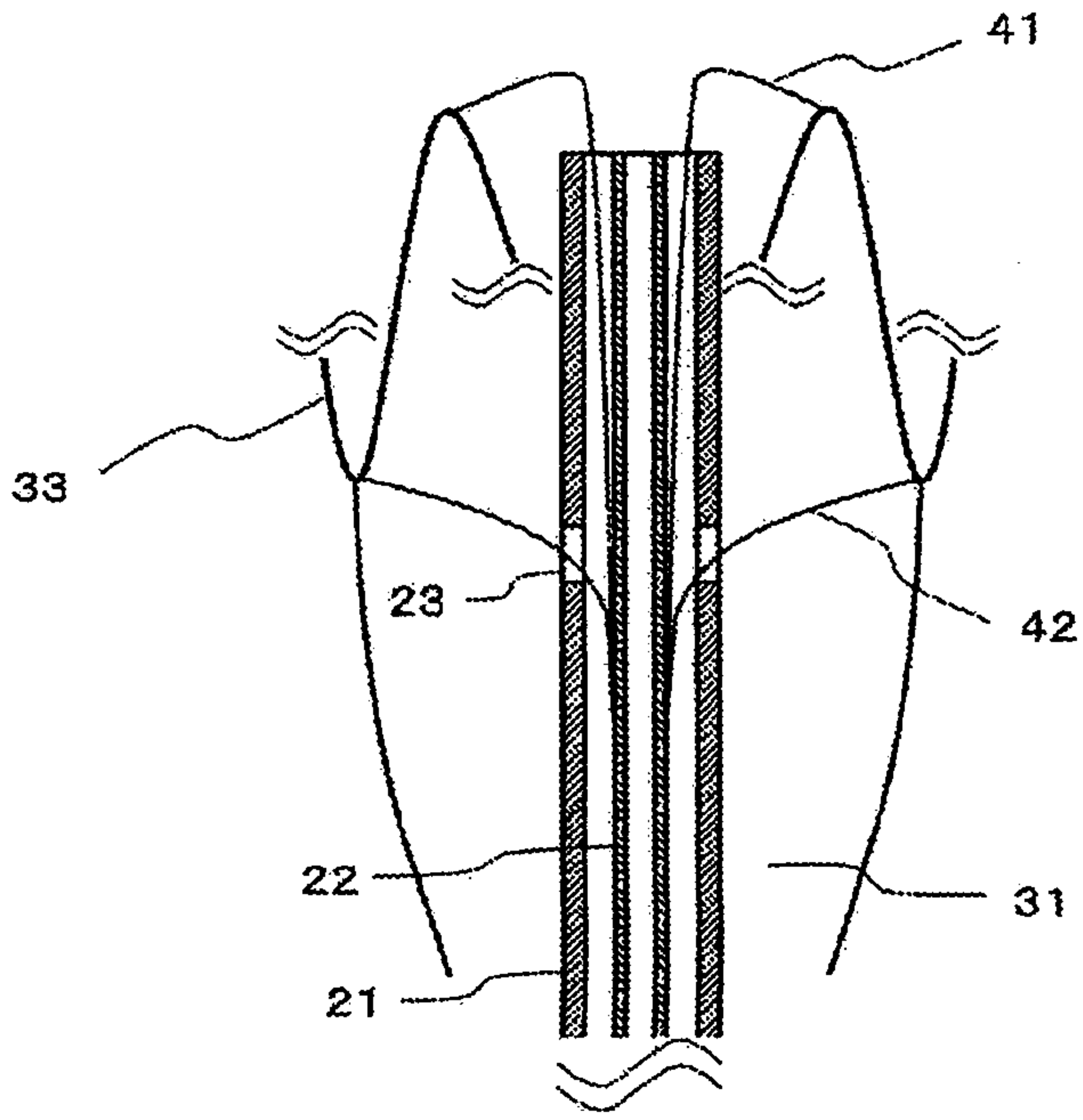


Fig. 9

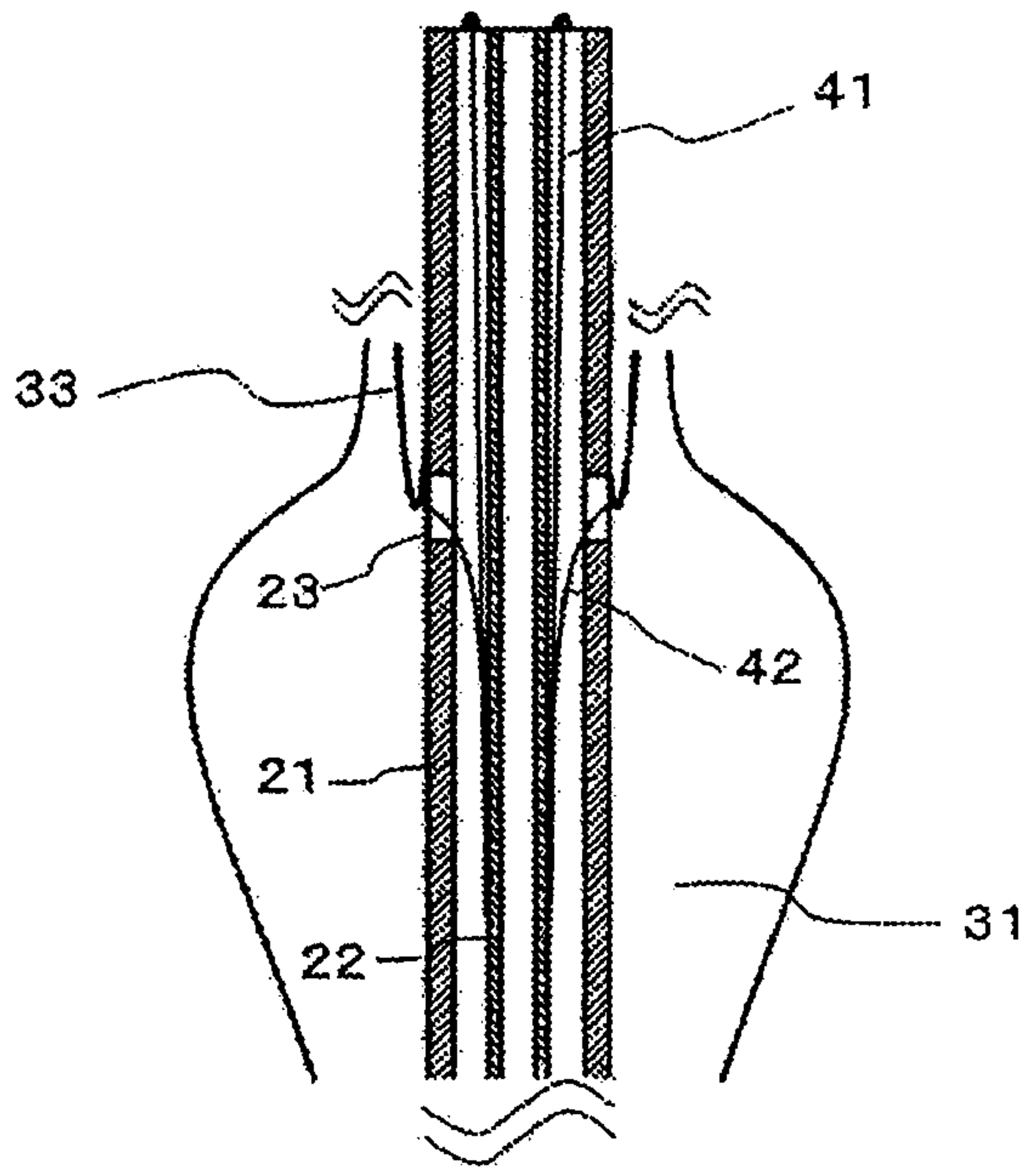


Fig. 10

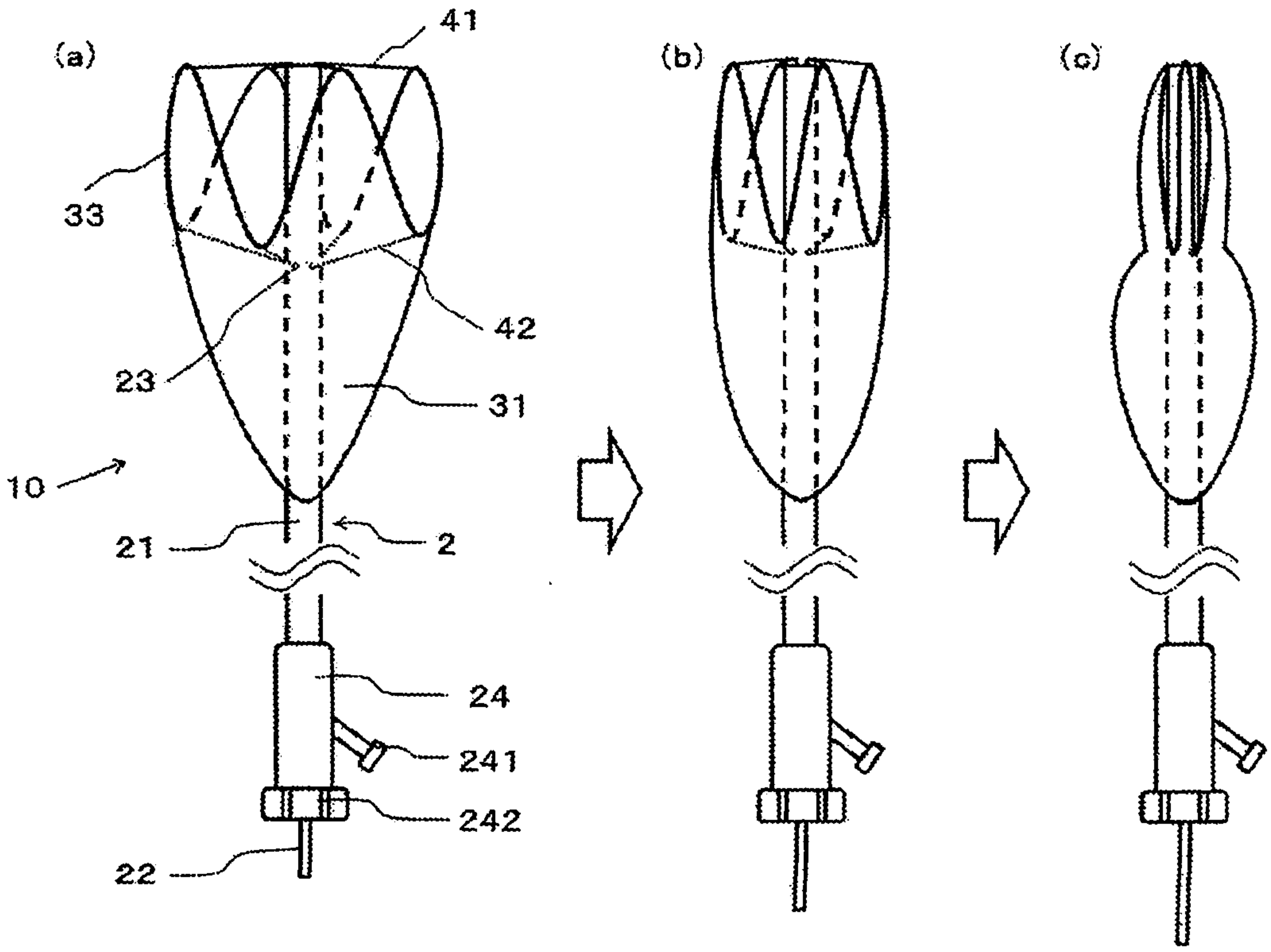


Fig. 11

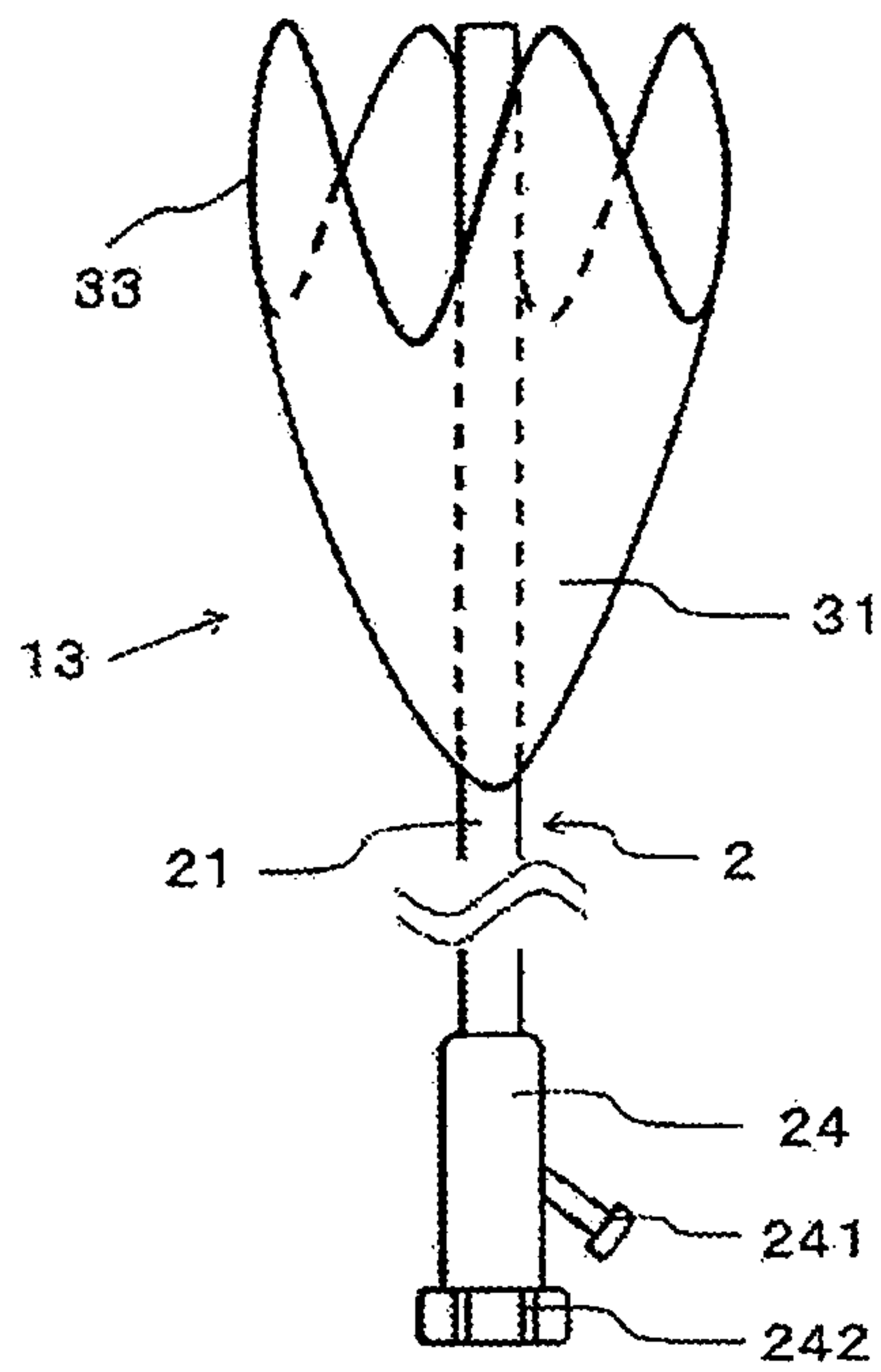


Fig. 12

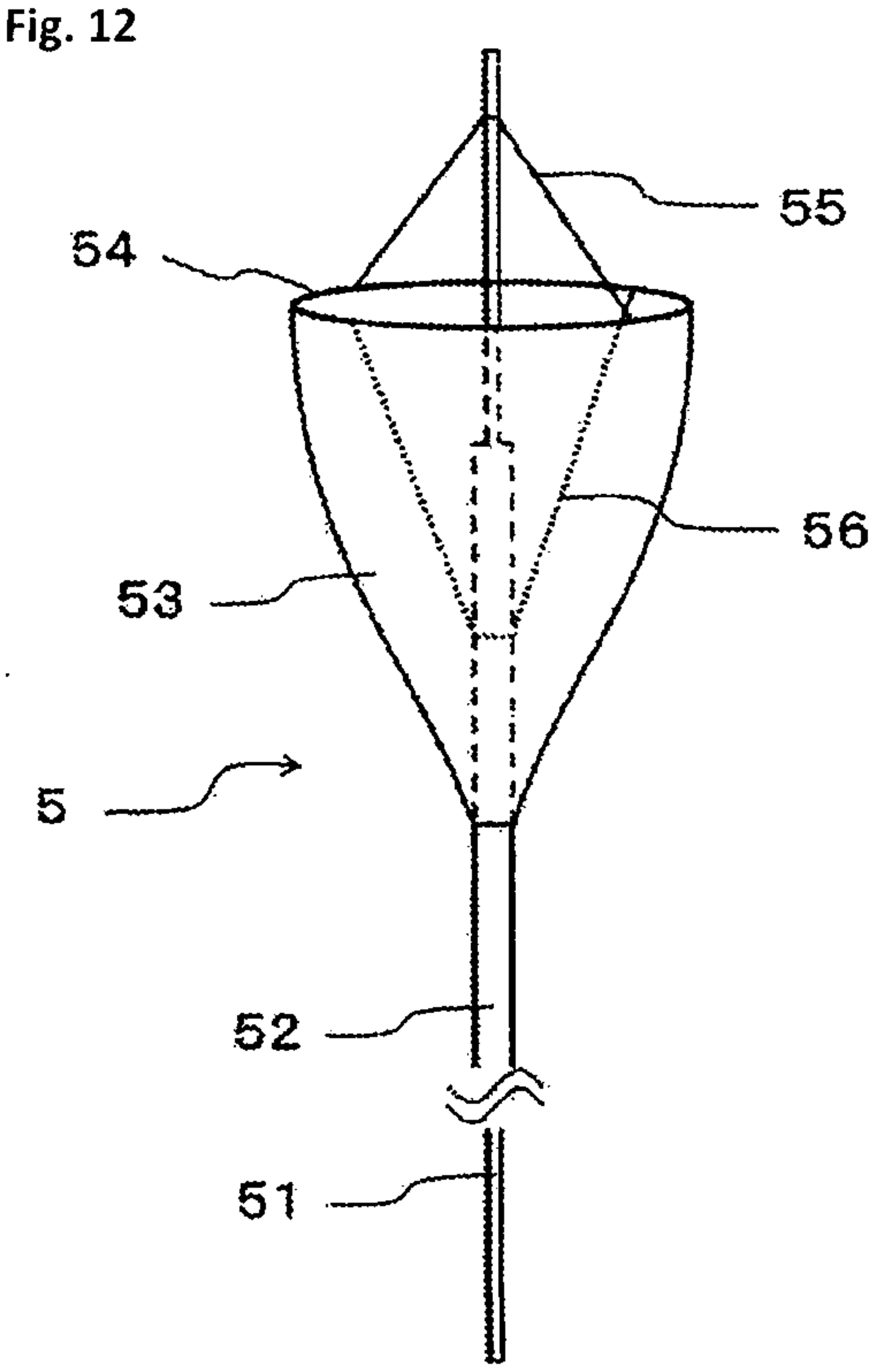
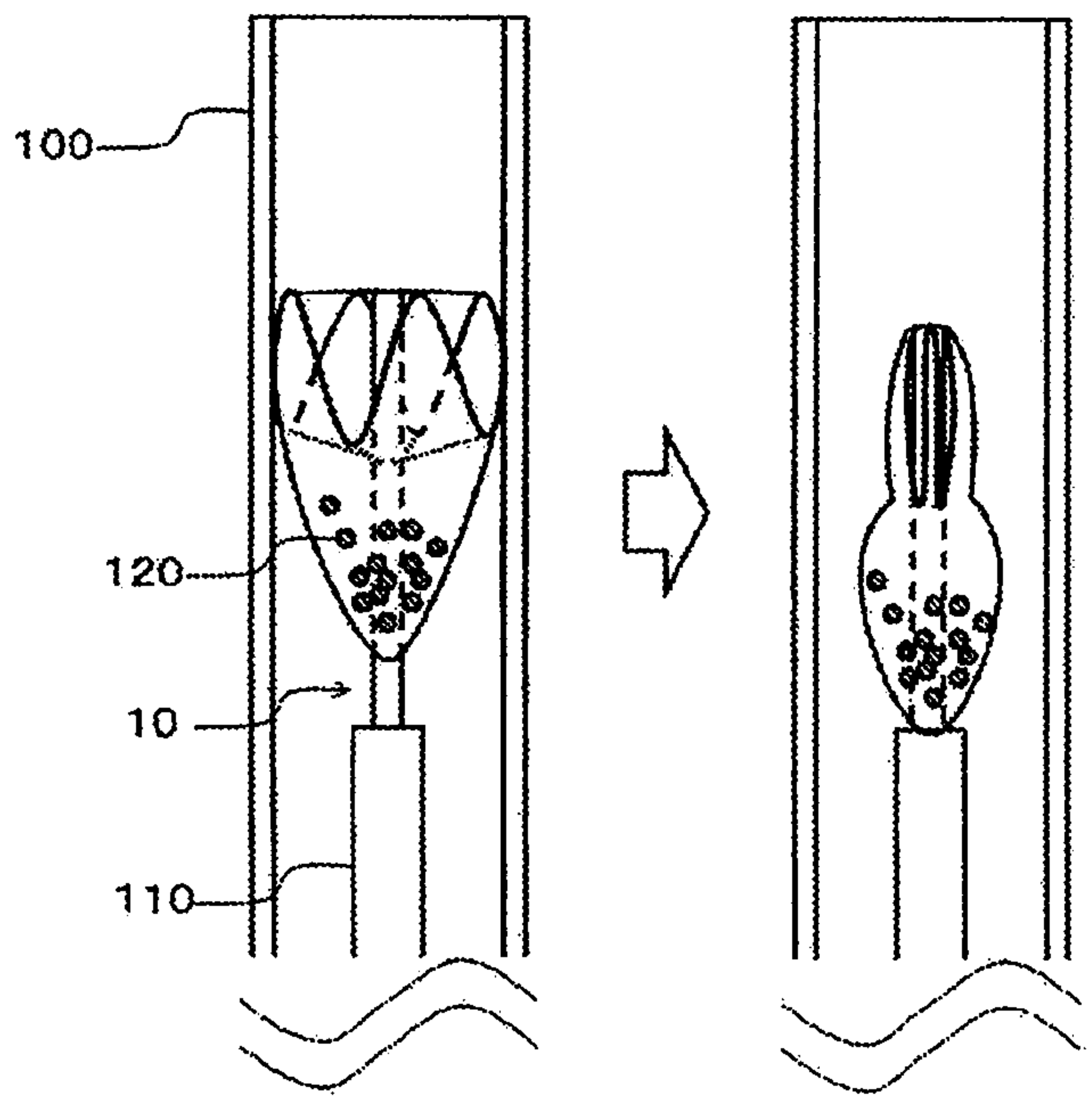


Fig. 13



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