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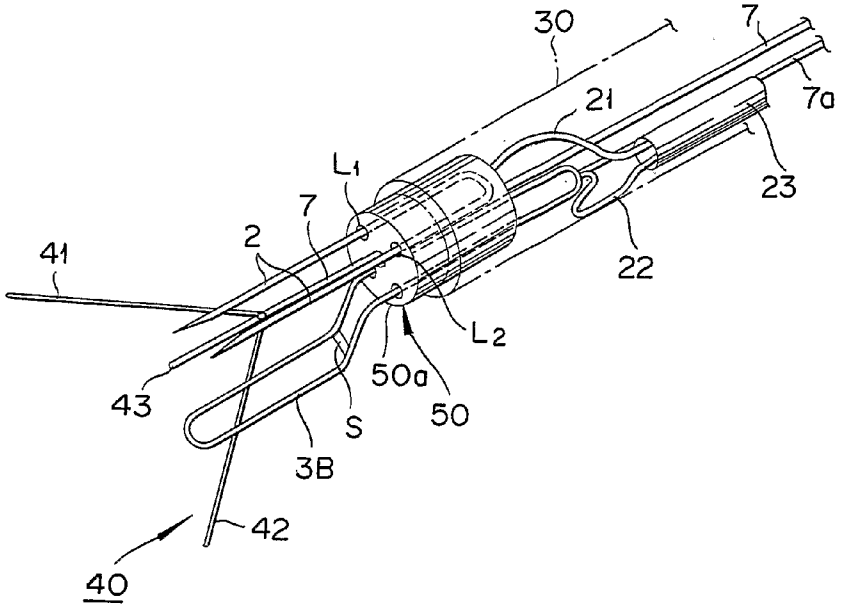
(54) **Title:** PFO CLOSING DEVICE



(57) **Abstract:** The present invention provides a PFO closing device for bringing septum primum and septum secundum into contact and joint with each other. The device includes clamping means and energy supplying means. The clamping means includes a needle part for puncturing the septum primum, and a clamping member for cooperating with the needle part in clamping therebetween the tissues having the septum primum and the septum secundum. The energy supplying means supplies energy for joining the tissues clamped by the needle part and the clamping member. The clamping means is mounted in a catheter so as to be protrudable from and retractable into the catheter.

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DESCRIPTION

PFO CLOSING DEVICE

BACKGROUND OF THE INVENTION

The present invention relates to a PFO closing device for closing a PFO generated in a heart.

Recently, the patent foramen ovale (hereinafter referred to as PFO) has come to be cited as a cardiac factor of stroke and migraine. The PFO is a symptom in which the oval foramen (foramen ovale) for shortcircuiting blood between the left and right sides in the heart in the fetal period of a person remains even after he is grown up, and it is said that 20-30% of grown-up people have this disease.

The PFO is generated in the septum secundum (hereinafter referred to as SP) of a heart. In a heart at normal time, the blood pressure in the left atrium of heart is higher than that in the right atrium of heart, so that the oval foramen is closed with the septum primum (hereinafter referred to as SP). However, when the blood pressure in the right atrium of heart comes to exceed that in the left atrium of heart in emergency (for example, at the time of coughing or straddling), the SP opens to the side of the left atrium of heart, resulting in that the blood flows from the side of the

right atrium of heart (the vein side) to the side of the left atrium of heart (the artery side). If thrombi are contained in the blood in this case, the thrombi are transferred from the vein side to the artery side, and flow from the left atrium of heart into the left ventricle, then into the aorta and into the brain, possibly causing stroke or migraine.

Examples of the treatment of such a disease include pharmacotherapy (aspirin, warfarin, or the like), closure of the PFO by percutaneous catheterization, and open heart surgery by extracorporeal circulation. The pharmacotherapy is the treatment which should be selected first, but it has the problem that it is difficult to manage the dose and that bleeding would not cease easily during the dosage. The percutaneous catheterization and the open heart surgery are radical treatments and remove the fear of recurrence, though they are attended by invasion. At the present stage, of these procedures of closure, the open heart surgery is more assured. However, taking into account the risk attendant on the extracorporeal circulation and the magnitude of the invasion attendant on skin incision, the treatment by percutaneous catheterization is more desirable, if it produces the same effect as that of the

open heart surgery.

Devices for closure by use of percutaneous catheterization can be used also in the cases of closing a defect, such as cogenital atrial septal defect (ASD), PFO, ventricular septal defect (VSD), patent ductus arteriosus (PDA), etc. The conventional devices, however, are based on clamping of the SP and the SS by use of a disk-like membrane or anchor member for closing the defect, and they are left indwelling in the patient's body.

The membrane and the anchor member are foreign matters for the body, and thrombi are liable to deposit thereon. Particularly, when a thrombus deposits on the disk-like membrane on the side of the left atrium of heart, it may flow downstream to cause stroke, or may break the SP which is small in wall thickness. In addition, these members may be positionally deviated, instead of being positionally fixed in the state of clamping the relevant tissues.

In view of these points, recently, there has been proposed the PFO closing device as described in WO2004/086944 A2 (refer to Abstract, FIG. 10, etc.).

In use of this PFO closing device, the appliance is passed through the PFO from the right atrium of heart

toward the left atrium of heart, the SP is drawn to the PFO to close the latter, and energy is applied thereto so as to join the tissues to each other. However, the PFO, the SP, and the SS differ not only in size but also in thickness, shape, and the like from patient to patient. In some cases, the dimensions of the appliance and the like would be restricted severely. Moreover, in the procedure of such a treatment, it may be difficult to draw always assuredly the SP, which differs in form from patient to patient, to the PFO.

SUMMARY OF THE INVENTION

The present invention has been made in order to solve the above-mentioned problems. Accordingly, it is an object of the present invention to provide a PFO closing device of simple configuration which makes it possible to join assuredly the SP and the SS to each other through easy procedure, without leaving any foreign matter indwelling in the patient's body.

According to the present invention, there is provided a PFO closing device for bringing SP (septum primum) and SS (septum secundum) into contact and joint with each other. The device includes clamping means having a needle part for puncturing the SP, and a

clamping member for cooperating with the needle part in clamping therebetween the tissues including the SP and the SS, and energy supplying means for supplying energy for joining the tissues clamped by the needle part and the clamping member. The clamping means is mounted in a catheter so as to be protrudable from and retractable into the catheter.

According to the present invention, there is also provided a PFO closing therapeutic method including a positioning step of positioning a needle part at a central portion of PFO, a holding step of holding SP (septum primum) so as to be non-retractable relative to the puncturing direction of the needle part, a puncturing step of causing the needle part to puncture the SP, a clamping step of bringing the SP and the SS into contact with each other by the needle part and a clamping member, and a joining step of passing an electric current in the needle part and the clamping member to thereby join the SP and the SS to each other.

In the present invention, the PFO closing device is wholly mounted in the catheter so as to be protrudable and retractable, so that by feeding the PFO closing device in the state of being retracted into the catheter, the device can be fed to a diseased (affected)

part comparatively easily. In the case of the procedure, also, since the tissues are clamped in the condition where the needle part has punctured the SP, the SP and the SS can be easily clamped, irrespectively of the variety in the forms of them. Particularly where the part to be fused is set at the entrance of the PFO as viewed from the side of the right atrium of heart and the SP is punctured by the needle part, the tissues can be assuredly joined to each other, without any influence of the degree of overlap of the membranes, the thickness and shape of the membranes, or the like arising from the individual differences in the shape of the SP.

In the case of clamping the tissues by the needle part and the clamping member, the tissues are clamped elastically (springy). Therefore, a press bonding force which follows up to the tissues shrunk by heating can be exerted sustainedly, so that the adhesion factors such as melted collagen and elastin can be press bonded in a desired shape.

Since a small-diameter and substantially rectilinear needle part is used as an electrode on one side of the clamping means, the tissues composed of the SP and the SS can be joined to each other without forming any hole greater than the needle-punctured hole,

so that leakage of blood can be minimized.

Since substantially the needle part and the clamping member or both of them together with holding means are only stored in the catheter, the present device is simple in configuration, which facilitates the procedure.

The present device, when having the holding means, holds the tissues composed of the SP and the SS at the time of puncturing. Therefore, the puncturing operation or the joining operation can be performed accurately and assuredly, whereby the procedure can be made to be accurate, speedy and easy.

Particularly where the present device has holding means including a positioning part for positioning the needle part relative to the PFO and a holding part for holding the SP so that the SP cannot be retracted relative to the needle part, the operation of positioning the needle part and the operation of holding the SP can be carried out in an undivided manner. Therefore, even a thin-walled SP can be punctured at a predetermined position, without breakage or damage. This enhances largely the safety and easiness of the procedure, and the procedure can be carried out accurately and speedily.

Particularly, the positioning and holding means ensures that the positioning of the needle part and the holding of the SP can be performed by only operating the operating member to move axially forwards or rearwards, so that the convenience or facility of the procedure is enhanced largely.

Preferably, the positioning and holding means has a main tube passed through the catheter and capable of being operated externally, an operating member provided in the main tube so as to be movable axially forwards and rearwards is protruded from the distal end of the main tube, an intermediate sleeve body and a tip sleeve body are provided coaxially with the operating member, and a contact member brought into contact with the tip sleeve body by pulling the operating member is provided at a distal end portion of the operating member. The tip sleeve body and the intermediate sleeve body are connected to each other by a first elastic wire member, and the intermediate sleeve body and the tip sleeve body are connected to each other by a second elastic wire member deformable more easily than the first elastic wire member. The second elastic wire member is curved outwards by pulling the operating member to thereby function as the positioning part making springy contact

with the inner edge of the PFO. The first elastic wire member between the tip sleeve body and the contact member and the intermediate sleeve body is curved by further pulling the operating member to thereby function as a holding part for holding the SP by the tip sleeve body and the contact member. This configuration ensures that the positioning and the holding of the SP can be performed more assuredly, thereby enhancing the safety, facility, accurateness, and speediness of the procedure.

Preferably, the positioning and holding means has a structure in which a main tube capable of being operated externally is protruded from the distal end of the catheter, an operating member movable axially forwards and rearwards is provided in the main tube, and an elastic second sleeve body is disposed at a distal end portion of the main tube. A positioning piece formed at a proximal portion of the second sleeve body is curved outwards by pulling, by the operating member, the second sleeve body protruded from the main tube, to thereby function as the positioning part making springy contact with the inner edge of the PFO, and a distal end portion of the second sleeve body is curved by further pulling the operating member to thereby function as a holding part for holding the SP from the side of the

left atrium of heart. This ensures not only the safety, facility, accurateness, and speediness of the procedure but also a simpler configuration of the PFO closing device.

Preferably, the positioning and holding means has a positioning part including a pair of elastic wire members protruded from a distal end portion of the catheter so as to be opened wider, and a holding part for holding the SP in a non-retractable manner by a projected part formed at the center of an M shape into which distal end portions of the elastic wire members are deformed. This ensures not only the safety, facility, accurateness, and speediness of the procedure but also a simpler configuration of the PFO closing device and inexpensiveness of the device.

The positioning and holding means has a main tube passed through said catheter and capable of being operated externally, an operating member provided in said main tube so as to be movable axially forwards and rearwards is protruded from the distal end of said main tube, an intermediate sleeve body and a tip sleeve body are provided coaxially with said operating member, and a contact member brought into contact with said tip sleeve body by pulling said operating member is provided at a

distal end portion of said operating member;

said main tube and said intermediate sleeve body are connected to each other by a first elastic wire member, said intermediate sleeve body and said tip sleeve body are connected to each other by a second elastic wire member and a third elastic wire member projectingly deformable more easily than said second elastic wire member;

said first elastic wire member is curved outwards by pulling said operating member to thereby function as said positioning part making springy contact with the inner edge of said oval foramen; and

by further pulling said operating member, said second elastic wire member is curved so that said tip sleeve body and said contact member function as a holding part for holding said septum primum, and said third elastic wire member is curved outwards to thereby function as a crease smoothing part for smoothing out creases present in said septum primum.

This also ensures not only the safety, facility, accurateness, and speediness of the procedure but also a simpler configuration of the PFO closing device.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic sectional view showing the use condition of a first embodiment of the present invention;

FIG. 2 is an enlarged perspective view of an essential part of the first embodiment;

FIG. 3 is a sectional view along line 3-3 of FIG. 2;

FIG. 4 is a sectional view showing the condition where a needle part is protruded from a catheter;

FIG. 5 is a sectional view showing the condition where tissues are gripped between the needle part and a gripping member;

FIG. 6 is a schematic perspective view showing a second embodiment of the present invention;

FIG. 7 is an enlarged sectional view of an essential part, showing the stored condition of the PFO closing device according to the second embodiment;

FIG. 8 is a schematic sectional view showing the condition where a gripping member is in contact with a guiding catheter;

FIG. 9 is a schematic sectional view showing the condition where the gripping member is pushed by the guiding catheter;

FIG. 10 is a schematic perspective view showing a

third embodiment of the present invention;

FIG. 11 is a front view of a support;

FIG. 12 is a side sectional view of the third embodiment;

FIG. 13 is a plan sectional view of the third embodiment;

FIG. 14 is a side sectional view of an essential part showing the gripping condition in the third embodiment;

FIG. 15 is a view showing the inserted condition of positioning means;

FIG. 16A is a front view of an PFO part as viewed from the side of a right atrium of heart R, and FIG. 16B is a sectional view along line B-B of FIG. 16A;

FIG. 17 is a view showing a puncture condition;

FIG. 18 is a view showing the puncture condition as viewed from the side of the left atrium of heart;

FIG. 19 is a view of a clamping condition as viewed from the side of the right atrium of heart;

FIG. 20 is a schematic perspective view showing a fourth embodiment of the present invention;

FIG. 21 is a front view of a support;

FIG. 22 is a side view of the fourth embodiment;

FIG. 23 is a plan sectional view of the fourth

embodiment;

FIG. 24 is a side sectional view of an essential part showing the gripping condition of the fourth embodiment;

FIG. 25 is a schematic perspective view of a PFO closing device according to a fifth embodiment of the present invention;

FIG. 26 is an end sectional view along line 26-26 of FIG. 25;

FIG. 27 is a sectional plan view of a hand-operated operating part of the PFO closing device;

FIGS. 28A to 28D are schematic views showing an operating condition of positioning and holding means in the fifth embodiment;

FIG. 29 is a schematic perspective view showing a sixth embodiment of the present invention;

FIG. 30 is a schematic perspective view showing a seventh embodiment of the present invention;

FIG. 31 is a schematic perspective view showing a deformed condition of the seventh embodiment;

FIG. 32 is a schematic perspective view showing an eighth embodiment of the present invention;

FIG. 33 is a schematic perspective view showing the condition where a SP in the eighth embodiment is

caught; and

FIG. 34 is an end view along line 33-33 of FIG. 32.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Now, some embodiments of the present invention will be described in detail below, referring to the drawings.

<First Embodiment>

FIG. 1 is a schematic sectional view showing the condition in use of a PFO closing device according to a first embodiment of the present invention, FIG. 2 is an enlarged perspective view of an essential part of the first embodiment, and FIG. 3 is a sectional view along line 3-3 of FIG. 2.

As shown in FIG. 1, the PFO closing device according to this embodiment generally has clamping means 1 for clamping a SP M2 and an SS M1, and energy supplying means 20 for supplying energy for joining the tissues clamped by the clamping means 1. The clamping means 1 is mounted in the distal end (tip) of a percutaneous catheter 30 so as to be protrudable and retractable (be movable forwards and rearwards). In use, the clamping means 1 in the state of being wholly stored in the catheter 30 is inserted in an inferior vena cava

J. In performing the procedure, the clamping means 1 is protruded from the distal end of the catheter 30, the tissues of the SS M1 and the SP M2 of a heart in which a defect O of Patent Foramen Oval (hereinafter referred also to simply as PFO O) is generated are clamped. In this condition, the tissues are joined by the energy supplied to the clamping means 1, whereby the defect O is closed.

More in detail, as shown in FIGS. 1 to 3, the clamping means 1 in this embodiment is a forceps-like clip composed of a needle part 2 for puncturing the SP M2, and a clamping member 3 cooperating with the needle part 2 in clamping the tissues composed of the SS M1 and the SP M2.

The needle part 2 has a structure in which two pointed wire members are fixedly attached to a distal end portion of a first plate 4, the clamping member 3 includes a second plate 5, and the first plate 4 and the second plate 5 are moved to open and close, with a base shaft 6 as a center. An operating member 7 is attached to the proximal (rear) end side of the first plate 4, and the whole part of the clamping means 1 is moved forwards and rearwards in the catheter 30 by moving the operating member 7 forwards and rearwards. The gripping

force between the needle part 2 and the clamping member 3 is generated by an urging means 8 (see FIG. 3), such as a spring, provided between the first plate 4 and the second plate 5.

Incidentally, while the operating member 7 is composed of a comparatively stiff wire member, it may not necessarily connected to the needle part 2 side, and may be connected to the clamping member 3. The operating member 7 may be any one that can move the clamping means 1 forwards and rearwards inside the catheter 30; preferably, for example, a wire of stainless steel, an Ni-Ti alloy, titanium, or the like is used as the operating member 7.

Particularly, in this embodiment, as shown in FIG. 2, the needle part 2 for puncturing the SP M2 has a structure in which two sharp-pointed extremely-small-diameter wire members are disposed with a spacing therebetween. When the SP M2 is punctured by such a needle part 2, the SP and the SS can be easily clamped, irrespectively of the shapes of them. The needle part 2 may not necessarily be solid, and may be hollow or annular. The outside diameter of the needle part 2 is preferably in the range of 0.1 to 2 mm, for mounting it in the catheter 30. As for the material of the needle

part 2, SUS is ordinarily used; however, other materials which do not exert bad influence on living bodies, such as gold, silver, platinum, tungsten, palladium, titanium, and alloys thereof can also be used. The spacing (interval) between the two needle parts 2 is not particularly limited, and may be in a certain range such that the SP M2 and the SS M1 can be clamped; in addition, the number of the needle parts 2 is not limited to two, and may be more.

The clamping member 3 may be a wholly flat plate-like member having a predetermined width so that it can cooperate with the needle parts 2 in clamping the tissues of the SS M1 and the SP M2 therebetween. In this embodiment, for preventing slip-off or displacement and achieve secure gripping, the clamping member 3 is provided with a rugged surface or rugged part 5a on the clamping face side. A traction wire 9 is connected to the proximal (rear) end of the clamping member 3 so that when the traction wire 9 is pulled axially rearwards, the clamping member 3 is opened away from the needle parts 2, with the base shaft 6 as a center, against the elasticity of the urging means 8. When the traction is relaxed, the clamping member 3 is closed toward the needle parts 2 by the elasticity of the urging means 8,

to achieve gripping. Incidentally, the traction wire 9 preferably has a structure, as for example shown in FIG. 3, in which a looped hook member 10 is provided at the proximal end of the first plate 4, and the traction wire 9 is extended to pass through the looped hook member 10, whereby the clamping member 3 can be smoothly opened and closed relative to the needle parts 2.

The energy supplying means 20, in this embodiment, is composed of an electricity supplying unit 20A for melting the SP M2 and the SS M1 electrothermally and press bonding with an adhesion factor such as collagen and elastin. Particularly, in the case of clamping by the needle part 2 and the clamping member 3, the elasticity of the urging means 8 is constantly applied during clamping. Therefore, it is possible to sustainedly applying a press bonding force which follows up to the tissues thermally contracted, and to press bond the adhesion factor such as collagen and elastin in a desired shape.

For example, one end of one lead wire 21 is connected to the proximal end of the needle parts 2, and one end of the other lead wire 22 is connected to the proximal end of the clamping member 3. The other ends of these lead wires 21 and 22 are contained in an

insulating tube 23, are guided through the catheter 30 to the exterior, and are connected to the electricity supplying unit 20A. The electricity supplying unit 20A is composed of a power supply, a control unit for controlling the current, etc., and it has a publicly known system configuration, the description of which is omitted here. Incidentally, the power supply may not necessarily be a DC power supply, and may be an AC power supply.

The energy supplying means 20 is not limited to the above-mentioned electrical one, and may be any one that can supply such an energy as to mutually join the SP M2 and the SS M1 clamped by the clamping means 1. For example, ultrasonic wave, laser, microwave, or high-frequency wave can be used as a source of energy. In addition, as the energy supply system, there can be used a monopolar system in which an electric current is passed between the needle parts 2 or the clamping member 3 on the side of the right atrium of heart R and a counter-electrode plate provided on the back side, a bipolar system in which an electric current is passed between the clamping member 3 on the side of the right atrium of heart R and the needle parts 2 on the side of the left atrium of heart L, or the like system.

Particularly, where a bipolar system in which an electric current is controlled according to the impedance of the tissues between the needle part 2 and the clamping member 3 is used as the energy supplying means 20, it is possible to easily cope with the conditions of the tissues of the SP M2 and the SS M1, which differ from patient to patient, and it is possible to obtain safety and facility of the procedure.

In this embodiment, the clamping means 1 is clip-like in form, and sliding friction may be generated between itself and the catheter 30, so that the needle parts 2 and the like are not liable to slip inside the catheter 30. In view of this, positioning means 40 (described later) for positioning the needle parts 2 at a predetermined position relative to the PFO O is not provided here. However, such positioning means 40 may be provided.

Now, operations of this embodiment will be described below.

FIG. 4 is a sectional view of the condition where the needle parts are protruded from the catheter, and FIG. 5 is a sectional view of the condition where the tissues are gripped between the needle parts and the gripping member.

First, the operator inserts a guide wire (not shown) into a patient's body, then passes a guiding catheter (not shown) while using the guide wire as a guide, and brings the guiding catheter forwards to the right atrium of heart R. When the distal end of the guide wire has reached the position of PFO of the heart and the guiding catheter has reached a position immediately before the PFO position, the position is maintained. Incidentally, where a radiopaque material (for example, gold, silver, platinum, tungsten, palladium, or alloys thereof) is provided as a so-called marker at, for example, the distal end of the guide wire, the catheter member 13 can be inserted while confirming the position thereof by irradiation with X-rays or the like, and the position in the patient's body can be grasped accurately.

Using as a guide the guide wire preliminarily located at the position of the PFO, the catheter 30 with the needle parts 2 and the clamping means 1 and the like stored therein is inserted through the inferior vena cava J into the patient's body, as shown in FIGS. 2 and 3. Though the catheter 30 is small in diameter and flexible as a whole, it can be easily inserted when the stiff guide wire is used as a guide. When the distal end

of the catheter 30 has protruded from the distal end of the guiding catheter and has reached the position of PFO, the guide wire is evulsed.

Subsequently, by operating the operating member 7, the needle parts 2 and the clamping member 3 for clamping are protruded from the catheter 30. Then, as shown in FIG. 4, by operating the operating member 7, the needle parts 2 protruding relative to the clamping means 3 are caused to puncture the SP M2 in the vicinity of the PFO O.

In this condition, the traction wire 9 is pulled axially rearwards (proximally), and both clamping member 1 and the needle parts 2 are opened against the urging means 8, with the base shaft 6 as a center, upon which the clamping member 3 is opened wider from the needle parts 2, so that the SS M1 and the SP M2 in a mutually overlapping state can be clamped between the clamping member 3 and the needle parts 2. In this clamping condition, the pulling force acting on the traction wire 9 is removed, upon which the SS M1 and the SP M2 between the clamping member 3 and the needle parts 2 are sustainedly pressed by the springy force of the urging means 8.

Then, the electricity supplying unit 20A is

controlled to supply a predetermined current through the lead wires 21 and 22, whereby the current is passed between the clamping member 3 and the needle parts 2, and both tissues of the SS M1 and the SP M2 are heated. While applying a press bonding force which follows up to the tissues contracted by the heating, the adhesion factor such as collagen and elastin thus melted is press bonded in a desired shape.

When the tissues are fused to each other, the passage of current is stopped, the traction wire 9 is pulled to space the clamping member 3 away from the tissues, and the needle parts 2 is evulsed from the SP M2. Though extremely tiny holes are left in the SP M2 after evulsion of the needle parts 2, they are cured thereafter. Therefore, there is no possibility of generation of thrombi or the like.

Then, the operating member 7 is operated to store the clamping means into the catheter 30 through the distal end of the latter, and the catheter 30 as a whole is evulsed from the patient's body.

<Second Embodiment>

FIG. 6 is a schematic perspective view of a PFO closing device according to a second embodiment of the present invention, FIG. 7 is an enlarged sectional view

of an essential part showing the stored condition of the PFO closing device, FIG. 8 is a schematic sectional view showing the condition where a gripping member is in contact with a guiding catheter, and FIG. 9 is a schematic sectional view showing the condition where the gripping member is pushed by the guiding catheter. Incidentally, in the following description, the same members as those described above are denoted by the same symbols as above, and descriptions of these members will be omitted.

The PFO closing device according to this embodiment is preferable, since clamping means 1 can be stored in a catheter 30 more compactly.

As shown in FIG. 6, the PFO closing device in this embodiment generally has a guiding catheter 31, the catheter 30, the clamping means 1, positioning means 40, and energy supplying means 20 (not shown in FIGS. 6 and 7). The guiding catheter 31 is provided at an outermost portion of the device. The catheter 30 is provided in the guiding catheter 31. The clamping means 1 includes needle parts 2 positionally fixedly provided inside the catheter 30 so as to protrude from the distal end of the catheter 30 and a clamping member 3A turnably provided in the outside of a distal end portion of the catheter

30. The positioning means 40 is for positioning the needle parts 2 at the center of the PFO O.

As shown in FIG. 7, the needle parts 2 constituting one side of the clamping means 1 has its base end (proximal end) fixedly attached to a distal end portion of the inside of the catheter 30 provided inside the guiding catheter 31, and its distal end portion is protruded from the distal end of the catheter 30, so that the needle parts 2 can puncture a desired tissue when the catheter 30 is protruded from the guiding catheter 31.

As shown in FIG. 6, the clamping member 3A constituting the other side of the clamping means 1 is composed only of a generally U-shaped wire member, of which the proximal ends (base ends) are slightly bent, and the bent proximal ends 11 are fitted in through-holes 12 opened in the catheter 30. Therefore, the clamping member 3A is attached to the catheter 30 so as to be turnable relative to the catheter 30. Accordingly, at the time of storage (in the condition where the catheter 30 is axially retracted relative to the guiding catheter 31), the clamping member 3A is in a rearwardly fallen position (hereinafter referred to as rearward inclined position) as shown in FIG. 7. On the other hand,

at the time of protrusion (in the condition where the catheter 30 is protruded relative to the guiding catheter 31), the external restrictive force exerted by the guiding catheter 31 is released, the clamping member 3A rises due to its own elasticity (see FIG. 8), and is pushed by a distal end portion of the guiding catheter 31, to be turned as indicated by arrow in FIG. 9. Thus, it is shifted from the dot-dash-line state to the solid-line state, to be put in a forwardly protruded position (hereinafter referred to as forward protruded position).

The clamping member 3A composed only of the U-shaped wire member may not necessarily be elastic, but it preferably has an outside diameter of 0.1 to 2 mm. As the material of the clamping member 3A, SUS is ordinarily used. However, other materials which do not exert bad effect on living bodies can also be used, for example, gold, silver, platinum, tungsten, palladium, titanium, or alloys thereof.

The positioning means 40 includes a pair of comparatively long elastic wire members 41, 42, and a cable-like operating member 7 connected to a bundled proximal end (base end) portion of the elastic wire members 41, 42, and is so provided that it can be moved forwards and rearwards in the catheter 30. Incidentally,

the cable-like operating member 7 may be slidably provided in a long tube, for contriving smoother operations. The pair of elastic wire members 41, 42 have their distal ends largely protruded relative to the distal ends of the needle parts 2 and opened wide to form a contained angle of about 90 degrees when their proximal end portions are located at the proximal (base) portion of the needle parts 2.

At the time of storage, the elastic wire members 41 and 42 are contracted under restraint by the guiding catheter 31. However, when the catheter 30 is protruded from the guiding catheter 31, the restraint is removed, and the elastic wire members 41 and 42 are opened wide. Therefore, when the elastic wire members 41 and 42 are protruded from the catheter 30 in the condition where the catheter 30 is protruded from the right atrium of heart R to the left atrium of heart L, the elastic wire members 41 and 42 make springy (elastic) contact with the aperture edge of the PFO O, and display a self-centering function due to the elasticity thereof.

Preferable specific examples of the elastic wire members 41, 42 are metal wires of stainless steel, nickel-titanium alloy, superelastic alloy (e.g., Ni-Ti alloy), or the like, with outside diameter of about 0.1

to 0.5 mm. Incidentally, the elastic wire members 41, 42 of the positioning means 40 may not necessarily be one pair, and may be provided in a greater number.

Now, operations of this embodiment will be described.

First, the operator operates the operating member 7 to obtain the condition where the needle parts 2 and the clamping member 3A and the like are stored in the inside of the catheter 30, as shown in FIG. 7. After the same operation as in the first embodiment has been conducted and the distal end of the guiding catheter 31 has reached the position of PFO, the catheter 30 is inserted into the guiding catheter 31.

When the distal end of the catheter 30 has been protruded from the right atrium of heart R through the PFO O to the left atrium of heart L, the operating member 7 is operated to protrude the pair of elastic wire members 41, 42 from the distal end of the catheter 30. This ensures that the elastic wire members 41, 42 are released from the restraint due to the guiding catheter 31, and are opened wide. When the elastic wire member 41, 42 are slightly moved rearwards (proximally) by the operating member 7 starting from the opened condition, the elastic wire members 41, 42 come to make

springy (elastic) contact with the aperture edge of the PFO O. As a result, the elastic wire members 41, 42 display a self-centering function due to the elasticity thereof, whereby the needle parts 2 are located at the center of the PFO O.

When the whole part of the catheter 30 together with the guiding catheter 31 in this condition is pushed forwards (distally), the needle parts 2 are caused to puncture the SP M2 in the vicinity of the PFO O. Besides, when the catheter 30 is pushed forwards (distally) relative to the guiding catheter 31, the clamping member 3A rises from the rear inclined position, as shown in FIG. 8. When the guiding catheter 31 is slightly moved forwards starting from this condition, the clamping member 3A is pushed by a distal end portion of the guiding catheter 31, to be turned into the forward protruded position, as shown in FIG. 9.

When the guiding catheter 31 is pushed further forwards, the clamping member 3A is pushed by the guiding catheter 31, and is displaced toward the side of the needle parts 2, to clamp the SS M1 and the SP M2 between itself and the needle parts 2.

While maintaining this clamping condition, the electricity supplying unit 20A is controlled to supply a

predetermined current through the lead wires 21 and 22 in the same manner as in the first embodiment, whereon a current is passed between the clamping member 3A and the needle parts 2, and the tissues of the SS M1 and the SP M2 are fused to each other.

After both the tissues are fused together, the passage of current is stopped, and the catheter 30 is retracted into the guiding catheter 31, whereby the positioning means 40, the clamping member 3A, and the like are stored, followed by evulsion of the guiding catheter 31 together with the catheter 30.

<Third Embodiment>

FIG. 10 is a schematic perspective view showing a third embodiment of the present invention, FIG. 11 is a front view of a support, FIG. 12 is a side view of the third embodiment, FIG. 13 is a plan view of the third embodiment, and FIG. 14 is a side view of an essential part showing the condition at the time of gripping in the third embodiment.

In this embodiment, a support 50 of a multilumen type is provided at the distal end (tip) of a catheter 30, and needle parts 2, a clamping member 3B, positioning means 40, and the like are passed respectively through the lumens in the support 50,

whereby compact and smooth operations are promised.

As shown in FIG. 10, this device has the support 50 positionally fixedly provided at a distal end portion in the catheter 30. As shown in FIG. 11, the support 50 has five lumens opened therein, the needle parts 2 are passed through first and second lumens L1 and L2, and they are positionally fixedly attached to the support 50. The clamping means 3B is passed through third and fourth lumens L3 and L4, and a cable-like operating member 7 of positioning means 40 is passed through a fifth lumen L5 at the center. It is to be noted here, however, that the support 50 may not necessarily be provided separately from the catheter 30; instead, a catheter 30 provided therein with a plurality of lumens (multilumen catheter) may also be used.

Energy supplying means 20 (see FIG. 1 or the like) has a structure in which one lead wire 21 is connected to the proximal end of the needle parts 2, the other lead wire 22 is connected to an operating member 7a for protruding and retracting the clamping member 3B through the support 50, and the lead wires 21 and 22 are connected to an electricity supplying unit 20A.

More in detail, as shown in FIG. 10, the clamping member 3B in this embodiment is composed of a single

elastic wire member which is formed to be arc-shaped at a distal end portion thereof and be hairpin-like in overall shape. In side view, as shown in FIG. 12, the clamping member 3B has a horizontal part "h" located inside the support 50, a bent part "f" formed at the distal end (tip) of the horizontal part 2a, and a distal end (tip) part "p" extending from the bent part "f" taperedly so as to gradually come away from the needle parts 2, so that the distance between the distal end of the distal end part "p" and the needle parts 2 is considerably large, as indicated by symbol X1.

Therefore, when the operating member 7a connected to the rear (proximal) side of the clamping member 3B is pulled, the wire member constituting the clamping member 3B receives a drag from the end portions of the lumens in the support 50, i.e., from the catheter side to be thereby deformed as a whole toward the needle parts 2, as shown in FIG. 14. The distance between the distal end of the distal end part "p" and the needle parts 2 is considerably reduced, as indicated by symbol X2 in FIG. 14.

Incidentally, in plan view, as shown in FIG. 13, the clamping member 3B is so set as to have a width comparable to that of the needle parts 3. In addition,

as shown in FIG. 10, in the vicinity of the bent part "f", there is provided a bridge-like stopper part S which abuts against the front face 50a of the support 50, thereby preventing the clamping member 3B from retracting more than necessary, in the case of retraction of the clamping member 3B into the support 50.

Positioning means 40 has a pair of elastic wire members 41, 42, in the same manner as in the second embodiment. In addition, a positioning wire 43 (see FIG. 13) which abuts on the PFO O is provided at a central position between the pair of elastic wire members 41, 42, and the operating member 7 is connected to a proximal end (base end) part formed by bundling them so that the positioning means 40 as a whole can be moved forwards and rearwards (distally and proximally) along the lumens in the support 50 by operating the operating member 7.

Incidentally, as the clamping member 3B, a SUS material with an outside diameter of 0.1 to 2 mm is used preferably. However, other materials which do not exert bad influence of living bodies may also be used, for example, gold, silver, platinum, tungsten, palladium, or alloys thereof, Ni-Ti alloy, titanium alloys, etc. As the operating member 7 and the positioning means 40, wire members formed of such material as SUS, gold,

silver, platinum, tungsten, palladium, alloys thereof, Ni-Ti alloy, titanium alloys, etc. and having an outside diameter of 0.1 to 0.5 mm can be used.

Now, operations of this embodiment will be described below.

FIGS. 15 to 19 show the procedure of operating the PFO closing device according to this embodiment.

First, the operator obtains the condition where the needle parts 2, the clamping member 3B, and the like are stored in the guiding catheter 31. Then, the guiding catheter 31 is inserted through the inferior vena cava J into the patient's body.

When a distal end portion of the guiding catheter 31 has reached the vicinity of the PFO O, an inserting operation is performed so that the distal end of the catheter 30 passes from the right atrium of heart R through the PFO O to protrude into the left atrium of heart L (see FIGS. 1, 4, and 5). When the distal end of the catheter 30 has protruded into the left atrium of heart L, the operating member 7 is operated so as to protrude the pair of elastic wire members 41, 42 from the distal end of the catheter 30, and the catheter 30 and the clamping member 3B are retracted. This ensures that the elastic wire members 41, 42 are opened wide,

and then the operating member 7a is operated so as to slightly return (move back) the elastic wire members 41, 42, whereby the elastic wire members 41, 42 are brought into springy contact with the aperture edge of the PFO O, as shown in FIG. 15 as viewed from the side of the left atrium of heart L. As a result, the self-centering function is displayed, in the same manner as in the above embodiments, whereby the needle parts 2 are located at the center of the PFO O. In addition, a proximal end portion of the positioning wire 43 abuts on an edge portion of the PFO O constituting an end portion of the SS M1, whereby the position of puncture by the needle parts 2 is secured more.

Here, FIG. 16A is a front view of the PFO portion as viewed from the side of the right atrium of heart R, and FIG. 16B is a sectional view along line B-B of FIG. 16A. In the condition where the elastic wire members 41, 42 are opened wide, as shown in FIG. 16A, the distal end part "p" of the clamping member 3B is located in the vicinity to be pressed of the SP M2, and the needle parts 2 are located nearly at the center of the PFO O. The positioning wire 43 abuts on an end portion of the SS M1, as shown in FIG. 16B, whereby the position of gripping at the entrance portion of the PFO O by the

needle parts 2 and the clamping member 3B is determined accurately. In addition, the positioning wire 43 also displays the function of pressing the SS M1 from the back side.

FIG. 17 is a view of the puncturing condition from the side of the right atrium of heart R, and FIG. 18 is a view of the puncturing condition from the side of the left atrium of heart L. In this condition, when the whole part of the catheter 30 is pushed forwards (distally) together with the guiding catheter 31, the needle parts 2 are made to puncture the SP M2 in the vicinity of the PFO O as shown in FIG. 18, and the clamping member 3B is also moved together with the needle parts 2, to a forwardly moved position, as shown in FIG. 17. Incidentally, the SP M2 is deformed into a sector shape due to the wide opening of the aperture edge of the PFO O by the elastic wire members 41, 42. At this stage, there is a spacing of about X1 between the clamping member 3B and the needle parts 2, so that the SS M1 and the SP M2 are simply located between the needle parts 2 and the clamping member 3B.

FIG. 19 is a view of the puncturing condition from the side of the right atrium of heart R. In this condition, when the operating member 7a of the clamping

member 3B is pulled axially rearwards, the clamping member 3B is retracted along the lumens in the support 50, the bent part "f" of the operating member 7a is deformed by end portions of the lumens in the support 50 toward the side of the needle parts 2, thereby firmly clamping the SS M1 and the SP M2 between itself and the needle parts 2. While maintaining this clamping condition, the electricity supplying unit 20A is controlled to supply a predetermined current through lead wires 21, 22, upon which the current is passed between the clamping member 3B and the needle parts 2, whereby the tissues of the SS M1 and the SP M2 are fused to each other.

When the tissues are thus fused together, the passing of current is stopped, the operating member 7 is pulled to retract the positioning means 40, the operating member 7a is operated to separate the clamping member 3B from the tissue, these members are retracted into the inside of the guiding catheter 31, to attain the storage condition, and the guiding catheter 31 is evulsed. While the tissues are gripped by moving the clamping member 3B by operating the operating member 7 in this embodiment, a method of clamping the tissues through a sliding operation of the guiding catheter 31

may also be adopted as in the above-described embodiment. Besides, the gripping of the tissues by the clamping member 3B may be conducted after evulsing the positioning means 40 after puncture.

<Fourth Embodiment>

FIG. 20 is a schematic perspective view showing a fourth embodiment of the present invention, FIG. 21 is a front view of a support, FIG. 22 is a side view of the fourth embodiment, FIG. 23 is a plan view of the fourth embodiment, and FIG. 24 is a side view of an essential part showing the gripping condition in the fourth embodiment.

This embodiment is basically the same as the third embodiment, except that the positioning means 40 and the gripping member (clamping member) 3B in the third embodiment are improved. As shown in FIGS. 20 and 21, a support 50 is provided with six lumens, needle parts 2 are passed through first and second lumens L1 and L2, and they are positionally fixedly attached to the support 50. The clamping member 3B is passed through third and fourth lumens L3 and L4, and the positioning means 40 is passed through fifth and sixth lumens L5 and L6 located at intermediate positions.

The positioning means 40 in this embodiment is

composed of a pair of elastic wire members 41, 42. The elastic wire members 41, 42 are independently inserted respectively in the fifth lumen L5 and the sixth lumen L6, are so bent as to be away from each other on the distal end (tip) side, thereby being opened wider, whereas they are bundled on the proximal (rear) end side, and connected to an operating member 7. Therefore, when the operating member 7 is operated, the elastic wire members 41, 42 are moved together forwards or rearwards along the lumens in the support 50, and are opened wider or contracted narrower under the restraint by the lumens L5, L6.

This ensures that the elastic wire members 41, 42 are supported by the lumens L5, L6. Therefore, even when a single operating member 7a is operated, the elastic wire members 41, 42 would not be rotated or be deviated in the rotating direction but, instead, retain securely their positions of abutment on the PFO O, whereby a centering function for needle parts 2 is displayed assuredly. In addition, the gripping member (clamping member) 3B in this embodiment is increased in diameter at a distal end part "p" thereof. By appropriately changing the outer diameter of the wire member itself constituting the gripping member (clamping member) 3B,

it is possible to display the same stopper effect as that of the above-mentioned bridge-like stopper part S and an effect of enhancing the gripping force. The distal end part "p" can be increased in diameter not only by locally changing the outer diameter so as to obtain a step but also by covering the wire member constituting the gripping member (clamping member) 3B with other member so as to obtain a tongue-like member. This makes it possible to press the SP M2 against the pair of needle parts 2 in a wider area, thereby enhancing the fusing property. The other member is preferably formed of the same material as the material of the gripping member (clamping member) 3B.

Now, operations of this embodiment will be described below. Since the operations of this embodiment are basically the same as those of the third embodiment, description will be made mainly as to the positioning means 40. When the distal end of the catheter 30 inserted along the guiding catheter 31 has passed from the right atrium of heart R through the PFO O to protrude into the left atrium of heart L, an operation of moving the single operating member 7 forwards (distally) is conducted. This ensures that the elastic wire members 41, 42 are protruded from the distal end of

the catheter 30, and the elastic wire members 41, 42 are spaced away from each other to come into the wide-opened state.

When the elastic wire members 41, 42 are slightly moved rearwards (proximally) by operating the operating member 7 starting from the wide-opened condition, the elastic wire members 41, 42 come into springy contact with the aperture edge of the PFO O, to display the self-centering function in the same manner as in the above embodiments, whereby the needle parts 2 are located at the center of the PFO O.

When the procedure is completed, the operating member 7 is pulled to retract the elastic wire members 41, 42 along the lumens in the support 50. After the elastic wire members 41, 42 are retracted into the inside of the guiding catheter 31 to obtain the storage condition, the guiding catheter 31 is evulsed. Besides, the gripping of the tissues by the clamping member 3B may be conducted after the positioning means 40 is evulsed after puncture, in the same manner as in the third embodiment. While the clamping member 3B is fixed by operating the operating member 7 in this embodiment, a method of gripping the tissues through a sliding operation of the guiding catheter 31 may be adopted, in

the same manner as in the above embodiments.

<Fifth Embodiment>

FIG. 25 is a schematic perspective view showing a PFO closing device according to a fifth embodiment of the present invention, FIG. 26 is an end view along line 26-26 of FIG. 25, and FIG. 27 is a sectional plan view of a hand-operated operating part of the PFO closing device.

In the above-described embodiments, there is no holding means for securely holding the SP M2 in a non-retractable manner at the time of puncturing with the needle parts 2. On the other hand, where means by which the holding means and the positioning means can be operated by a series of operations (hereinafter referred to as positioning and holding means) is adopted, the puncturing with the needle parts 2 is facilitated. In addition, the speediness and assuredness of the procedure are greatly enhanced, which naturally is preferable. Particularly, since the SP M2 is a membrane with a small thickness of about 1 to 2 mm, it is liable to be broken or damaged. In view of this, when the SP M2 is held from the back side at the time of puncture, the procedure can be conducted safely, without putting an irrational burden on the SP M2. This is extremely

preferable.

Incidentally, the configuration of this embodiment is similar to those of the above-described embodiments, in regard of other points than the positioning and holding means. Therefore, the same members as those in the above embodiments are denoted by the same symbols as used above, and descriptions of them will be omitted in the following description.

As shown in FIG. 25, the positioning and holding means 60 in this embodiment generally has a positioning part 61 for positioning the needle parts 2 in relation to the PFO O, and a holding part 62 for holding the SP M2 non-retractably in relation to the puncturing direction of the needle parts 2. The positioning and holding means 60 is so configured that, when a long operating member 7 provided in a catheter 30 to be movable forwards (distally) and rearwards (proximally) is protruded from the distal end of the catheter 30 and is moved axially forwards or rearwards, the positioning part 61 and the holding part 62 can thereby be operated continuously.

The positioning and holding means 60 is provided at a distal end portion of the catheter 30 provided therein with a plurality of lumens L (L is the generic

symbol for lumens L1-L5 shown in FIG. 26) formed along the axial direction, and is normally stored in a guiding catheter 31. At the time of use, the positioning and holding means 60 is pushed out from the guiding catheter 31.

The catheter 30 in this embodiment is one obtained by elongating the above-mentioned support 50, and is provided therein with five lumens. An elastic main tube 63 and the operating member 7 provided in the main tube 63 to be movable forwards and rearwards are passed through the lumen L5 so that the positioning part 61 and the holding part 62 are operated by a hand-operated operating part 70 connected to the proximal end side of the operating member 7. Incidentally, in the following description, the hand-operated operating part side of the PFO closing device will be referred to as "the proximal side", and the side of the needle parts 2 or the SP M2 will be referred to as "the distal side".

More in detail, the positioning and holding means 60 includes the positioning part 61 and the holding part 62. The positioning part 61 includes the main tube 63, the operating member 7, and a pair of first elastic wire members 66. The main tube 63 is provided in the central lumen L5 having the maximum aperture diameter, of the

five lumens L1-L5, for reinforcing the catheter 30 and recovering by pulling the positioning and holding means 60 into the catheter 30. The operating member 7 is provided to be movable axially forwards and rearwards in the main tube 63. The pair of first elastic wire members 66 moves to open wider and contract narrower by the operating member 7 and connecting the main tube 63 and an intermediate sleeve body 64 to each other. The holding part 62 includes a contact member 68 provided at a distal end portion of the operating member 7, a tip sleeve body 65, and a pair of second elastic wire members 67 connecting the intermediate sleeve body 64 and the tip sleeve body 65 to each other, so as to hold the SP M2 by the contact member 68 and the tip sleeve body 65.

The positioning part 61 centers the needle parts 2 relative to the PFO O by protruding the operating member 7 from the distal end of the main tube 63, and operating the operating member 7 to move axially forwards or rearwards, thereby displacing the first elastic members 66 outwards so that the first elastic members 66 presses the inner edge of the PFO O with springy forces which are substantially equal. In short, the positioning part 61 displays the function by which the needle parts 2

located between the first elastic members 66 are located at a central portion of the PFO O.

The holding pat 62 has a curving mechanism W for curving a distal end portion of the operating member 7 by operating the operating member 7 to move axially forwards or rearwards. The curving mechanism W displays the function of curving the holding part 62 oppositely to the direction of puncturing the SP M2 with the needle parts 2, so as thereby to hold the SP M2. The curving mechanism W has the intermediate sleeve body 64, the tip sleeve body 65, the second elastic wire members 67 connecting the sleeve bodies 64, 65 to each other, and the contact member 68.

The proximal ends of the first elastic wire members 66 are welded to the distal end of the main tube 63, and the distal ends thereof are welded to the intermediate sleeve body 64. On the other hand, the proximal ends of the second elastic wire members 67 are welded to the distal end of the intermediate sleeve body 64, and the distal ends thereof are welded to the tip sleeve body 65.

Preferable specific examples of the first and second elastic wire members 66, 67 are metal wires formed of stainless steel, nickel-titanium alloy,

superelastic alloy (e.g., Ni-Ti alloy) or the like, with an outer diameter of about 0.1 to 0.5 mm. In addition, the metal wire may be covered with a resin (flexible) tube, for preventing the elastic wire members 66, 67 from damaging the tissues.

Particularly, the holding part 62 is so configured that the first elastic wire members 66 on the proximal side are curved prior to the second elastic wire members 67 on the distal side, to position the needle parts 2, and then the operating member 7 itself is deformed while being accompanied by the contact member 68 and the tip sleeve body 65, so as to hold the SP M2 after the needle parts 2 are positioned by the positioning part 61.

Such a configuration is not particularly limited. For example, there may be adopted a method in which the second elastic wire members 67 are formed of a material higher in stiffness than that for the first elastic wire members 66, a method in which a part of the first elastic wire members 66 is preliminarily worked by bending or the like to form easily deformable parts so that the first elastic wire members 66 are curved prior to the second elastic wire members 67 through deformation of the easily deformable parts when a pulling force is exerted thereon, or the like method.

This ensures that, with only the operating member 7 pulled rearwards, the first elastic wire members 66 on the proximal side come into abutment on the inner edge of the PFO O, thereby positioning the needle parts 2. With the operating member 7 pulled further, the second elastic wire members 67 on the distal side are deformed in the manner of projecting in an arcuate shape radially outwards, whereby the SP M2 can be held non-retractably so that the puncture with the needle parts 2 can be performed easily.

As shown in FIGS. 25 and 26, the hand-operated operating part 70 generally includes a first operating body 73 and a second operating body 76. The proximal end of the catheter 30 is connected through a connecting member 71 and a Y connector 72 to the first operating body 73. The second operating body 76 is provided with through-holes 75 permitting passage therethrough of a pair of slide rails 74 projected from the proximal end of the first operating body 73 and which can move toward and away from the first operating body 73 by sliding along the slide rails 74. Incidentally, in FIG. 25, only the hand-operated operating part 70 is shown with reduction, for convenience of space.

The main tube 63 is passed through the inside of

the first operating body 73, and its proximal end is connected to the distal end of the second operating body 76. Therefore, with the second operating member 76 pulled rearwards, the whole part of the positioning and holding means 60 can be recovered into the central lumen L5 of the catheter 30. Incidentally, the main tube 63 may be formed of a deformable elastic material such as polyimide resin, polyurethane, PET, nylon, fluoro-resin, polypropylene, etc. In addition, the hand-operated operating part 70 may be formed by use of a metallic pipe and be connected to the main tube 63 formed of an elastic material.

The proximal end of the operating member 7 is attached to a grip 78 reciprocally slid in a slide groove 75 formed in the center of the second operating body 76. With the grip 78 slid reciprocally in the slide groove 75, the whole part of the operating member 7 is reciprocated in the main tube 63.

As shown in FIG. 27, the slide groove 75 is so formed that the width A1 of a front half portion thereof is greater than the width A2 of a rear half portion thereof. This ensures that, in the case where the grip 78 is located in the front half of the slide groove 75, the grip 78 can be inclined to a direction orthogonal to

the axis of the slide groove 75, whereby the operating member 7 can be turned about its axis inside the catheter 30, so as to rotate and adjust the position of its distal end. As a result, when the operating member 7 is operated by operating the grip 78 in the hand-operated operating part 70, not only the position in the front-rear direction but also the rotational position can be adjusted, which enhances greatly the facility of the procedure of inserting the device into the left atrium of heart.

The needle part 2 constituting one side of the clamping means 1 may be formed in a U-shaped overall form and be inserted in a lumen formed by breaking the partition portion between the lumens L1 and L2; or, the individual needle part 2 may be disposed respectively in the lumens L1 and L2. In any case, a lead wire is connected to the rear end(s) of the needle part(s) 2, and the lead wire is drawn through the Y connector 72 to the exterior, to be connected to the energy supplying means 20 through a coupler 77.

The clamping member 3B constituting the other side of the clamping means 1 has a structure in which a distal end portion of a generally U-shaped wire member is covered with a conductive material to obtain a

tongue-like member. The proximal ends of the wire member are passed through the lumens L3 and L4 of the catheter 30, and are connected to a single operating member 7a. The operating member 7a is operative to move the clamping member 3B forwards and rearwards. In this embodiment, the operating member 7a is connected on the proximal side to a distal end portion of the second operating body 76.

The lead wires relevant to the operating member 7a and the needle parts 2 are led through the Y connector 72 to the exterior, and are connected to the electricity supplying unit 20A through a predetermined switch.

Now, operations of this embodiment will be described below. FIGS. 28A to 28D are schematic views showing the operating conditions of the positioning and holding means. Incidentally, while the actual shapes and positions of the second elastic wire members 66 are substantially flush with those of the needle parts 2 and the clamping member 3B, they are shown in the state of having been displaced by 90 degrees, for ease of understanding. Therefore, the deformed conditions shown in the figures are different from the actual deformed conditions.

First, the operator retracts the second operating

body 76 of the hand-operated operating part 70 in relation to the first operating body 73, to obtain the condition where the needle parts 2, the clamping member 3B, and the like are stored in the guiding catheter 31. In this condition, using a guide wire as a guide by the ordinary method, the distal end of the guiding catheter 31 is inserted into the patient's body from a predetermined position of the body, to the right atrium of heart R. Incidentally, there may be adopted a method in which only the guiding catheter 31 is inserted into the patient's body, and thereafter the catheter 30 is inserted by use of the guiding catheter 31 as a guide.

Next, by operating the first operating body 73, the distal end of the catheter 30 is passed from the right atrium of heart R through the PFO O to protrude into the left atrium of heart L. Thereafter, the grip 78 is moved forwards to thereby protrude the distal end of the operating member 7 from the tip sleeve body 65 and insert it into the left atrium of heart L. This protruded condition can be visually confirmed externally if the contact member 68 or the like is provided with a marker. However, if the protrusion is accompanied by abutment of the distal end of the operating member 7 against the inside wall of the left atrium of heart L or

the like, the place where the distal end of the operating member 7 is located can be tactually confirmed, even where visual confirmation is difficult to achieve. This enhances facility. Incidentally, where the grip 78 is located in the wider front half portion of the slide groove 75 and is inclined, the tactual confirmation of the position of the distal end of the operating member 7 is facilitated.

After the position of the distal end of the operating member 7 is confirmed, the grip 78 is retracted until the contact member 68 of the operating member 7 abuts on the tip sleeve body 65, as shown in FIG. 28B (the retraction amount is "δ1" in FIG. 28B). Then, the first operating body 73 is operated to locate the second elastic wire members 67, the needle parts 2, and the clamping member 3B in the vicinity of the SP M2, and the whole body of the holding part 62 is inserted into the left atrium of heart L.

With the grip 78 retracted further (the retraction amount is "δ2" in FIG. 28C), the operating force of the retraction is transmitted by the operating member 7 and through the contact member 68, the tip sleeve body 65, the second elastic wire members 67, and the intermediate sleeve body 64 to the first elastic wire members 66

firmly attached to the distal end of the main tube 63. The first elastic wire members 66 are deformed in the manner of projecting in arcuate shapes radially outwards, as shown in FIG. 28C. It should be noted here, however, the second elastic wire members 67 are not yet deformed in this instance.

As a result, the first elastic wire members 66 are deformed while pressing wider the aperture edge portion of the PFO O, so that the needle parts 2 proximate to the first elastic wire members 66 are centered relative to the PFO O, i.e., the needle parts 2 are located in the center of the PFO O.

With the grip 78 retracted further until the proximal end of the intermediate sleeve body 64 abuts on the distal end of the main tube 63, as shown in FIG. 28D, the first elastic wire members 66 are not considerably deformed, whereas the second elastic wire members 67 on the distal side are deformed in the manner of projecting in arcuate shapes radially outwards, under the above-mentioned operating force. As a result, inside the left atrium of heart L, the contact member 68 and the tip sleeve body 65 come closer to the needle parts 2, so that the contact member 68 and the tip sleeve body 65 abut on the face on the left atrium side of the SP M2,

to hold the latter.

In this condition, the first operating body 73 is moved forwards, whereby the needle parts 2 provided at the distal end of the catheter 30 puncture the SP M2 at predetermined positions. The puncture condition is the condition shown in FIG. 1 in which the SS M1 and the SP M2 are present between the needle parts 2 and the clamping member 3B.

Once puncturing is done, the position of the needle parts 2 is fixed in relation to the SP M2. At this stage, therefore, the second operating body 75 is once returned to make the first elastic wire members 66 and the second elastic wire members 67 straight, as shown in FIG. 28B. Then, the second operating body 75 is retracted so that the whole body of the positioning and holding means 60 is recovered into the lumen L5 of the catheter 30 by the main tube 63.

At the time of this recovery, the operating member 7a of the clamping member 3B connected to the second operating body 75 also retracts the clamping member 3B along the lumens of the catheter 30, so that the bent part "f" of the clamping member 3B are deformed by an end portion of the catheter 30 toward the needle parts 2, to firmly clamp the SS M1 and the SP M2 between itself

and the needle parts 2.

While maintaining this clamping condition, the electricity supplying unit 20A is controlled so as to pass a predetermined current between the clamping member 3B and the needle parts 2, whereby the tissues of the SS M1 and the SP M2 are fused to each other.

When the tissues are fused together, the passing of current is stopped, the first operating body 75 is retracted so that the needle parts 2 and the clamping member 3B located at the distal end of the catheter 30 are stored into the guiding catheter 31 together with the positioning and holding means 60, and the guiding catheter 31 is evulsed from the patient's body.

<Sixth Embodiment>

FIG. 29 is a schematic perspective view showing a sixth embodiment of the present invention. While the positioning and holding means 60 in the fifth embodiment has had a configuration in which the first elastic wire members 66 in the positioning part 61 and the second elastic wire members 67 in the holding part 62 are composed of separate members, this embodiment adopts a configuration in which the two kinds of elastic wire members are integrated, to obtain a simpler configuration.

Positioning and holding means 80 in this embodiment has a configuration in which the proximal end of a second sleeve body 81 is mounted to a main tube 63 protruded by a predetermined length from the distal end of a catheter 30, an operating member 7 provided in the main tube 63 is protruded from the distal end of the second sleeve body 81, and a contact member 68 is provided at the protruded distal end of the operating member 7.

A positioning part 61 is composed of a pair of positioning pieces 82 formed at a proximal (base) portion of the second sleeve body 81. In this case, the positioning pieces 82 are formed by slitting or cutting off a part of the second sleeve body 81, leaving end portions of the second sleeve body 81. Incidentally, the positioning pieces 82 are preferably formed in the shape of flat bands so that they make springy (elastic) contact with the inner edge of the PFO O.

On the other hand, a holding part 62 has a configuration as follows. The second sleeve body 81 protruded from the main tube 63 is provided with two through-holes 83 and 84 spaced in the axial direction. The operating member 7 led from the main tube 63 into the second sleeve body 81 is once drawn out to the

exterior via the through-hole 84, is then returned into the second sleeve body 81 via the through-hole 83, and is further extended and protruded from the distal end of the second sleeve body 81. A contact member 68 is provided at the protruded distal end of the operating member 7.

Here, the second sleeve body 81 may be any tube that is deformable. Preferably, however, the second sleeve body 81 is a tube which can be visually confirmed externally by use of X-rays or the like, and is preferably composed of a synthetic resin such as polyurethane, PET, nylon, polyethylene, polyimide, fluoro-resin, polypropylene, etc.

In use of the positioning and holding means 80 configured as above, when the operating member 7 is pulled by an operation, the contact member 68 abuts on the distal end of the second sleeve body 81, and the operating force in this instance acts on the whole part of the second sleeve body 81 through the contact member 68. The positioning pieces 82 formed at a proximal (base) portion of the second sleeve body 81 are lower in stiffness than the other portions because of the formation of the slit or cutout. Therefore, the positioning pieces 82 are preferentially curved outwards,

as if they were buckled, to abut on the inside surface of the PFO O, thereby displaying a centering function, whereby the needle parts 2 are positioned at predetermined positions.

With the operating member 7 pulled further, the second sleeve body 81 between the through-holes 83 and 84 is curved, resulting in that the SP M2 is held by the contact member 68 and the second sleeve body 81a on the distal side relative to the through-hole 83.

The positioning and holding means 80 in this embodiment thus has a configuration in which the second sleeve body 81 is mounted to the main tube 63 protruded from the catheter 30, and the second sleeve body 81 is provided with the positioning pieces 82 at a proximal (base) portion thereof and with the two through-holes 83 and 84 in a distal end (tip) portion thereof. Therefore, the positioning and holding means 80 in this embodiment is simpler in configuration and advantageous in cost, as compared with that in the above-described embodiment.

Incidentally, operations of the positioning and holding means 80 in this embodiment are substantially the same as in the fifth embodiment above. Therefore, the description of the operations is omitted.

<Seventh Embodiment>

FIG. 30 is a schematic perspective view showing a seventh embodiment of the present invention, and FIG. 31 is a schematic perspective view showing a deformed condition of the seventh embodiment. Positioning and holding means 90 according to this embodiment is similar in configuration to that in the fifth embodiment, except that it has a crease smoothing part 91 for smoothing out creases of the SP M2. The shapes of the PFO O and the SP M2 differ from person to person; particularly, the SP M2 has creases, which make it difficult to specify the position of puncture by needle parts 2. If the needle parts 2 can be made to puncture the center of the SP M2 in the condition where the creases are smoothed out, the smoothness and facility of the procedure are enhanced, with the result that the assuredness of the treatment is enhanced, and the procedure can be carried out safely and speedily, which is extremely preferable.

In view of this, the positioning and holding means 90 in this embodiment generally has a positioning part 61 for positioning the needle part 2 in relation to the PFO O, a holding part 62 for holding the SP M2 non-retractably in relation to the puncturing direction of the needle parts 2, and the crease smoothing part 91 for smoothing out the creases present in the SP M2.

This embodiment is the same as the fifth embodiment above in that the positioning part 61 and the holding part 62 can be continuously operated by moving a long operating member 7 axially forwards and rearwards, but this embodiment is different from the fifth embodiment in the point of the crease smoothing part 91. Therefore, this point will be described, and descriptions of the other parts, denoted by the same symbols as used above, will be omitted.

As shown in FIG. 30, the crease smoothing part 91 is composed of a pair of third elastic wire members 92 connecting an intermediate sleeve body 64 and a tip sleeve body 65 to each other. In the positioning and holding means 60 in the above-described embodiment, the intermediate sleeve body 64 and the tip sleeve body 65 have been connected by only one pair of second elastic wire members 67. On the other hand, in the positioning and holding means 90 in this embodiment, the pair of third elastic wire members 92 are provided on the outside of the second elastic wire members 67.

The third elastic wire members 92, in the pre-deformation state shown in FIG. 30, are deformed in the manner of projecting radially outwards in substantially same plane as first elastic wire members 66. It is

preferable that the third elastic wire members 92, in the post-deformation state as shown in FIG. 31, are opened radially outwards so largely as to smooth out the creases of the SP M2. In consideration of this point, in this embodiment, the third elastic wire members 92 are composed of members which are deformable in the manner of projecting outwards more easily than the first elastic wire members 66. To be more specific, the third elastic wire members 92 are the same as the first elastic wire members 66 in outer diameter and material, but are larger in length than the first elastic wire members 66. Incidentally, while the third elastic wire members 92 as shown in the figure are curved to some extent, they may be curved more outwards.

In use of the positioning and holding means 90 configured as above, in the same manner as in the above-described embodiments, the distal end of a catheter 30 is passed from the right atrium of heart R through the PFO O to protrude into the left atrium of heart L, the distal end of an operating member 7 is protruded from the tip sleeve body 65 and inserted into the left atrium of heart L. Then, the operating member 7 is retracted until its contact member 68 abuts on the tip sleeve body 65, and the holding part 62 is inserted into the left

atrium of heart L.

With the operating member 7 retracted, the operating force is transmitted through the contact member 68, the tip sleeve body 65, the second elastic wire members 67, and the intermediate sleeve body 64 to the first elastic wire members 66 firmly attached to the distal end of a main tube 63, whereby the first elastic wire members 66 are deformed in the manner of projecting radially outwards into arcuate shapes. Where the projecting deformation of the first elastic wire members 66 is performed in the vicinity of the PFO O, the needle parts 2 can be centered in relation to the PFO O. It should be noted here, however, that the second elastic wire members 67 and the third elastic wire members 92 are not yet deformed in this instance.

With the operating member 7 retracted further, as shown in FIG. 31, the second elastic wire members 67 on the distal side are curved. In addition, the third elastic wire members 92 are deformed in the manner of projecting radially outwards into arcuate shapes. In this case, the third elastic wire members 92 are deformed in directions such as to smooth out the creases of the SP M2, i.e., in directions such as to projectingly deform along the plane of the SP M2, which

is generally deviated by about 90 degrees from the plane in which the first elastic wire members 66 are deformed projectingly.

As a result, the contact member 68 and the tip sleeve body 65 hold the SP M2 from the side of the left atrium of heart L, whereas the third elastic wire members 92 on the side of the right atrium of heart R enter into the creases of the SP M2, to smooth out the creases.

Therefore, the operator can assuredly puncture a predetermined position of the SP M2, held by the holding part 62 from the side of the left atrium of heart L and with its creases smoothed out, by the needle parts 2 located in the center of the PFO O.

After the predetermined position of the SP M2 is punctured with the needle part 2, the whole body of the positioning and holding means 90 is recovered into a lumen L5 of the catheter 30 by the main tube 63, whereon the SS M1 and the SP M2 are firmly clamped between a clamping member 3B and the needle parts 2. While maintaining this clamping condition, an electric current is passed between the clamping member 3B and the needle parts 2, whereby the tissues of the SS M1 and the SP M2 are fused together.

<Eighth Embodiment>

FIG. 32 is a schematic perspective view showing an eighth embodiment of the present invention, FIG. 33 is a schematic perspective view showing the condition where the SP M2 is caught in the eighth embodiment, and FIG. 34 is an end view along line 34-34 of FIG. 32.

The positioning and holding means 60, 80, and 90 in the above-described embodiments are so configured that the SP M2 is held after positioning and that the positioning operation and the holding operation are to be conducted sequentially. On the other hand, in this embodiment, the positioning operation and the holding operation can be conducted substantially at a stroke, and the configuration therefor is extremely simplified.

As shown in FIG. 32, positioning and holding means 100 in this embodiment includes a positioning part 61 composed of a pair of comparatively long elastic wire members 101 projected in a fanned manner from a distal end portion of a catheter 30, and a holding part 62 in which a projecting part 102 is centrally formed by deforming the distal end (tip) portions of the elastic wire members 101 into a substantially M-shaped form.

As shown in FIG. 34, the pair of elastic wire members 101 may be connected to the distal end of an

operating member 7 passed through a central lumen L5, of a plurality of lumens L1-L5 formed in the catheter 30, or the two elastic members 101 themselves may be passed through the central lumen L5, to be led to a hand-operated operating device provided at a base portion of the device. In any way, the proximal end (base) portions of the elastic wire members 101 are extended along tapered grooves 103 formed in side portions of the catheter 30. The tapered grooves 103 are so formed as to go from outer peripheral surfaces of the side portions of the catheter 30 gradually toward the inside of the catheter, so that the angle formed between the elastic wire members 101 can be set to a desired opening angle by regulating the inclination angle of the tapered grooves 103. Moreover, since the elastic wire members 101 are operated along the tapered grooves 103, the elastic wire members 101 can be smoothly protruded from and retracted into the lumen L5 of the catheter 30, which promises good operationality.

Distal end (tip) portions of the elastic wire members 101 are bent comparatively sharply to the inner side, and are then directed to the proximal side at a central area, to obtain a roughly M-shaped overall form, and to form the projecting part 102 there. The

projecting part 102 serves as a part for holding the SP M2 in relation to the puncturing direction of the needle parts 2, from the back side.

As is clear from FIG. 1, in the case of holding the SP M2 from the back side, it is preferable to set the projecting part 102 in the state of being inclined against the plane formed by both the elastic wire members 101. In the positioning and holding means 100 in this embodiment, therefore, after a guiding catheter 31 is inserted into the left atrium of heart, the projecting part 102 is projected from an end portion of the guiding catheter 31, as shown in FIG. 33, so that the SP M2 can be easily caught and held.

When the guiding catheter 30 is pulled into the right atrium of heart starting from the condition where the SP M2 is thus held by the projecting part 102, the elastic wire members 101 are pulled and developed into a fanned form, to make springy contact with the inner peripheral edge portion of the PFO O, whereby the needle part 2 are positioned substantially in the center of the PFO O. The projecting part 102 formed at the center of the elastic wire members 101 projects to the back side of the SP M2, namely, to the side of the left atrium of heart, so as to hold the SP M2.

While maintaining this holding condition, the catheter 30 is moved forwards, whereby the needle parts 2 are made to puncture the SP M2. After the puncture, the elastic wire members 101 are moved forwards, and are moved from the side of the left atrium of heart to the side of the right atrium of heart. Then, the elastic wire members 101 are recovered into the tapered grooves 103 in the catheter 30, and the projecting part 102 is recovered into the lumen L5.

Then, in the condition where the needle parts 2 and the clamping member 3B clamp the interatrium septum M1 and the SP M2 therebetween, an electric current are passed therebetween, whereby the tissues of the interatrium septum M1 and the SP M2 are fused together.

The positioning and holding means 100 in this embodiment has a structure in which tip portions of the pair of elastic wire members 101 opened wider at a predetermined angle are deformed into the roughly M-shaped form. Therefore, it is extremely simplified in configuration and advantageous on a cost basis, as compared with those in the above-described embodiments.

The present invention is not limited to the above-described embodiments, and various modifications can be made by those skilled in the art within the scope of the

technical thought of the invention. For example, while the above embodiments are for use in a therapeutic procedure of closing a defect of PFO, the application of the present invention is not limited to this case. For example, the invention is applicable also to the case of closing a passage-like defect, such as the case of a left atrial appendage.

In addition, while the PFO closing devices in the above embodiments are each simply stored in a catheter and the clamping means is operated through the operating member, this configuration is not limitative. For example, the PFO closing device can be combined with a so-called balloon catheter, to be fed to a predetermined position.

The present invention can be utilized as a PFO closing device by which a defect portion of PFO can be closed easily and safely.

CLAIMS

[1] A PFO closing device for bringing septum primum and septum secundum into contact and joint with each other, said device comprising:

clamping means including a needle part for puncturing said septum primum, and a clamping member for cooperating with said needle part in clamping therebetween the tissues having said septum primum and said septum secundum; and

energy supplying means for supplying energy for joining said tissues clamped by said needle part and said clamping member;

wherein said clamping means is mounted in a catheter so as to be protrudable from and retractable into said catheter.

[2] The PFO closing device as set forth in claim 1, wherein said clamping means is a forceps-like clip such that said clamping member is opened and closed relative to said needle part, with a base shaft as a center.

[3] The PFO closing device as set forth in claim 1, wherein said clamping means has a structure in which either one of said needle part and said clamping member is fixedly attached to a distal end portion of said catheter provided in a guiding catheter, and the other

of said needle part and said clamping member is turned toward said one of said needle and said clamping member through an axial displacement of said catheter relative to said guiding catheter, so as thereby to clamp said tissues between said needle part and said clamping member.

[4] The PFO closing device as set forth in claim 3, wherein said clamping member includes a wire member attached to said catheter so as to be turnable.

[5] The PFO closing device as set forth in claim 1, wherein said clamping means includes said needle part fixedly attached to a distal end portion of said catheter, and said clamping member provided at a distal end portion of said catheter so as to be movable axially forwards and rearwards, and said clamping member is moved axially forward and rearwards, whereby a bent part of said clamping member is caused by a drag from said catheter side to come closer to and away from said needle part.

[6] The PFO closing device as set forth in any of claims 1 to 5, wherein said clamping means has springy means for exerting a springy force in such a direction as to urge said needle part and said clamping member closer to each other.

[7] The PFO closing device as set forth in claim 6, wherein said clamping member includes a tongue-like member.

[8] The PFO closing device as set forth in any of claims 1 to 7, further comprising positioning means for positioning said needle part at a predetermined position relative to the PFO.

[9] The PFO closing device as set forth in claim 8, wherein said positioning means includes at least one pair of elastic wire members protruded largely beyond the distal end of said needle part.

[10] The PFO closing device as set forth in any of claims 1 to 9, further comprising positioning and holding means which includes a positioning part for positioning said needle part relative to the PFO, and a holding part for holding said septum primum so as to be non-retractable relative to the puncturing direction of said needle part.

[11] The PFO closing device as set forth in claim 10, wherein said positioning and holding means has a crease smoothing part for smoothing out creases present in said septum primum.

[12] The PFO closing device as set forth in claim 10, wherein said positioning and holding means has a

structure in which a long operating member provided in said catheter so as to be movable forwards and rearwards can be protruded from the distal end of said catheter, and said positioning part and said holding part can be operated continuously by operating said operating member axially forwards or rearwards.

[13] The PFO closing device as set forth in claim 10 or 11, wherein said positioning and holding means can be turned inside said catheter, with the axis of said operating member as a center.

[14] The PFO closing device as set forth in claim 10 or 12, wherein said positioning part of said positioning and holding means has a structure in which said long operating member provided in said catheter so as to be movable forwards and rearwards is protruded from the distal end of said catheter, and an elastic member is displaced outwards by operating said operating member to move axially forwards or rearwards, whereby said needle part is positioned in a central portion of said PFO through elastic contact of said elastic member with the inner edge of said PFO.

[15] The PFO closing device as set forth in claim 10 or 12, wherein said holding part of said positioning and holding means has a curving mechanism for curving a

distal end portion of said long operating member provided in said catheter so as to be movable forwards and rearwards, by protruding said operating member from the distal end of said catheter and operating said operating member to move axially forwards or rearwards, and a distal end portion of said operating member holds said septum primum so as to be opposite to the direction in which said needle part punctures said septum primum.

[16] The PFO closing device as set forth in claim 15,

wherein said curving mechanism

has a main tube passed through said catheter and capable of being operated externally, an operating member provided in said main tube so as to be movable axially forwards and rearwards is protruded from the distal end of said main tube, an intermediate sleeve body and a tip sleeve body are provided coaxially with said operating member, said tip sleeve body and said intermediate sleeve body are connected to each other by an elastic wire member, and a contact member brought into contact with said tip sleeve body by pulling said operating member is provided at a distal end portion of said operating member; and

said tip sleeve body and said contact member

brought into contact with each other by operating said operating member to move forwards or rearwards curve said elastic wire member and are displaced so as to hold said septum primum.

[17] The PFO closing device as set forth in claim 10 or 12,

wherein said positioning and holding means

has a main tube passed through said catheter and capable of being operated externally, an operating member provided in said main tube so as to be movable axially forwards and rearwards is protruded from the distal end of said main tube, an intermediate sleeve body and a tip sleeve body are provided coaxially with said operating member, and a contact member brought into contact with said tip sleeve body by pulling said operating member is provided at a distal end portion of said operating member;

said main tube and said intermediate sleeve body are connected to each other by a first elastic wire member, and said intermediate sleeve body and said tip sleeve body are connected to each other by a second elastic wire member deformable more easily than said first elastic wire member;

said first elastic wire member is curved outwards

by pulling said operating member to thereby function as said positioning part making springy contact with the inner edge of said PFO; and

said second elastic wire member is curved by further pulling said operating member to thereby function as a holding part for holding said septum primum by said tip sleeve body and said contact member.

[18] The PFO closing device as set forth in claim 10 or 12,

wherein said positioning and holding means

has a structure in which a main tube capable of being operated externally is protruded from the distal end of said catheter, an operating member movable axially forwards and rearwards is provided in said main tube, and an elastic second sleeve body is disposed at a distal end portion of said main tube; and

a positioning piece formed at a proximal portion of said second sleeve body is curved outwards by pulling, by said operating member, said second sleeve body protruded from said main tube, to thereby function as said positioning part making springy contact with the inner edge of said PFO, and a distal end portion of said second sleeve body is curved by further pulling said operating member to thereby function as a holding part

for holding said septum primum from the side of the left atrium of heart.

[19] The PFO closing device as set forth in claim 10 or 12,

wherein said positioning and holding means has a positioning part including a pair of elastic wire members protruded from a distal end portion of said catheter so as to be opened wider, and a holding part for holding said septum primum in a non-retractable manner by a projected part formed at the center of an M shape into which distal end portions of said elastic wire members are deformed.

[20] The PFO closing device as set forth in claim 13,

wherein said positioning and holding means has a main tube passed through said catheter and capable of being operated externally, an operating member provided in said main tube so as to be movable axially forwards and rearwards is protruded from the distal end of said main tube, an intermediate sleeve body and a tip sleeve body are provided coaxially with said operating member, and a contact member brought into contact with said tip sleeve body by pulling said operating member is provided at a distal end portion of

said operating member;

said main tube and said intermediate sleeve body are connected to each other by a first elastic wire member, said intermediate sleeve body and said tip sleeve body are connected to each other by a second elastic wire member and a third elastic wire member projectingly deformable more easily than said second elastic wire member;

said first elastic wire member is curved outwards by pulling said operating member to thereby function as said positioning part making springy contact with the inner edge of said PFO; and

by further pulling said operating member, said second elastic wire member is curved so that said tip sleeve body and said contact member function as a holding part for holding said septum primum, and said third elastic wire member is curved outwards to thereby function as a crease smoothing part for smoothing out creases present in said septum primum.

[21] The PFO closing device as set forth in any of claims 3 to 8, wherein said catheter is fitted at its distal end portion with support means having a plurality of lumens, and said needle part, said clamping member, and an operating member of said positioning means are

passed through said lumens.

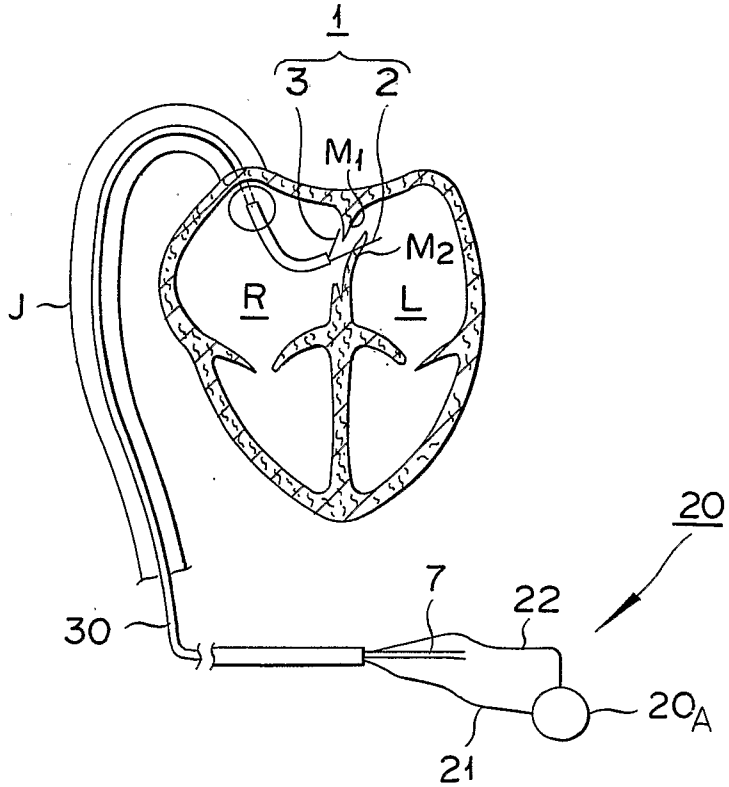
[22] The PFO closing device as set forth in any of claims 1 to 10, wherein said needle part has a structure in which a plurality of wire members circular or circularly annular in section orthogonal to the axis and having an outside diameter of 0.1 to 2 mm are mutually spacedly disposed.

[23] The PFO closing device as set forth in claim 1, wherein said energy supplying means is of a high-frequency monopolar system in which an electric current is passed between said needle part or said clamping member and a counter electrode plate provided extracorporeally.

[24] The PFO closing device as set forth in claim 1, wherein said energy supplying means is of a high-frequency bipolar system in which an electric current is passed between said needle part and said clamping member.

[25] The PFO closing device as set forth in claim 24, wherein said energy supplying means is of a high-frequency bipolar system in which an electric current is passed by utilizing the impedance of a tissue between said needle part and said clamping member.

FIG. 1



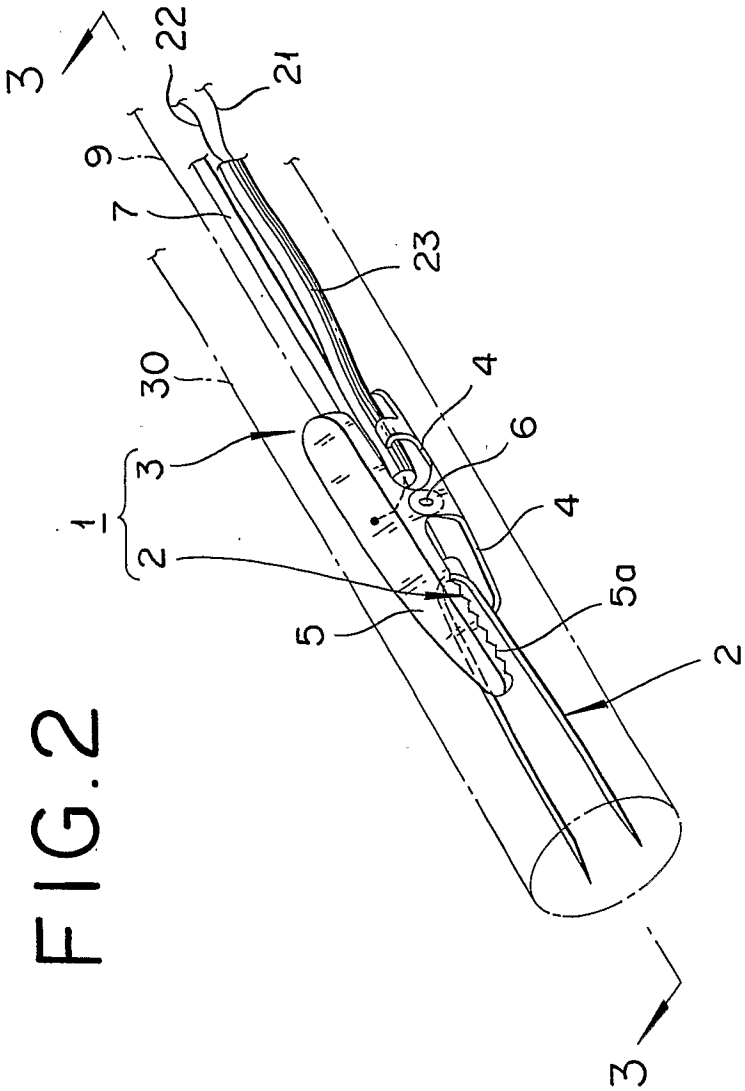


FIG.2

FIG.3

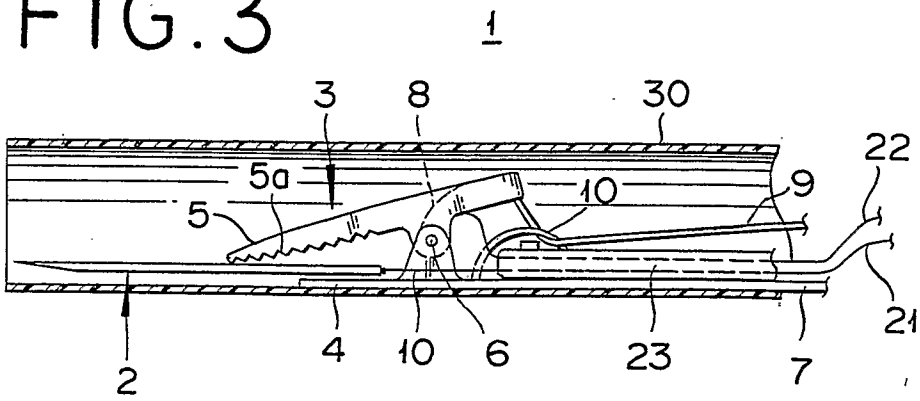


FIG.4

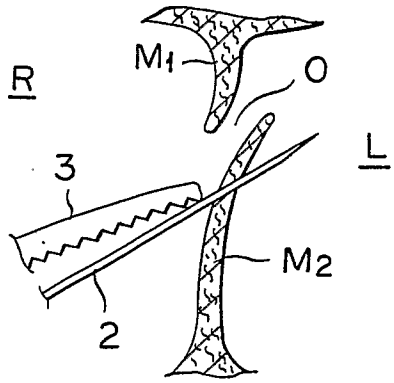


FIG.5

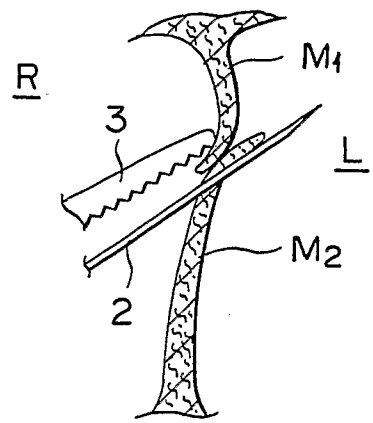


FIG.6

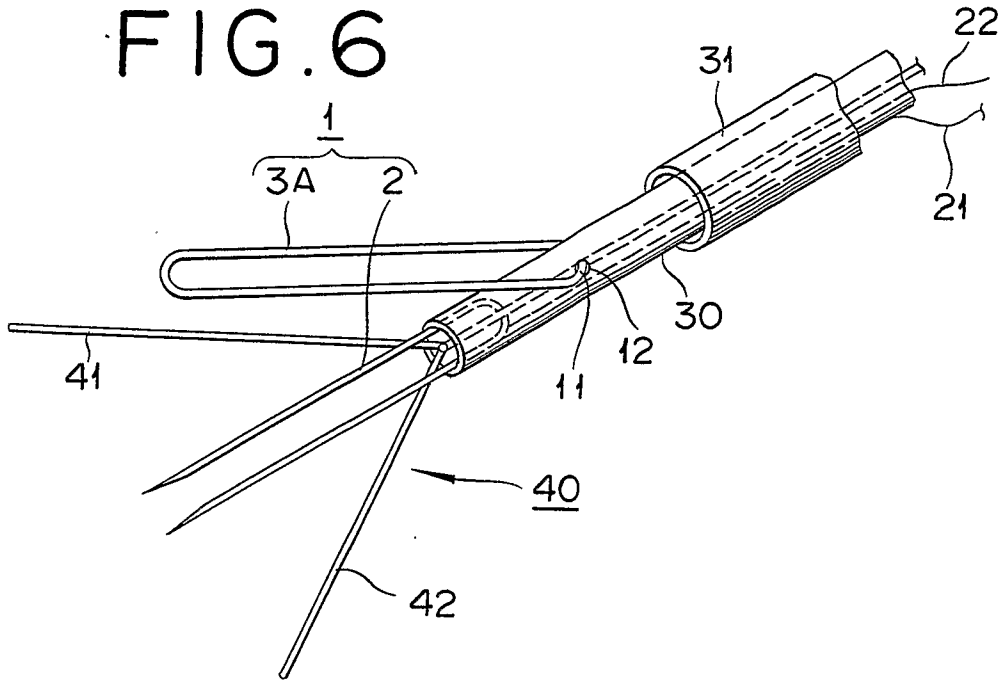


FIG. 7

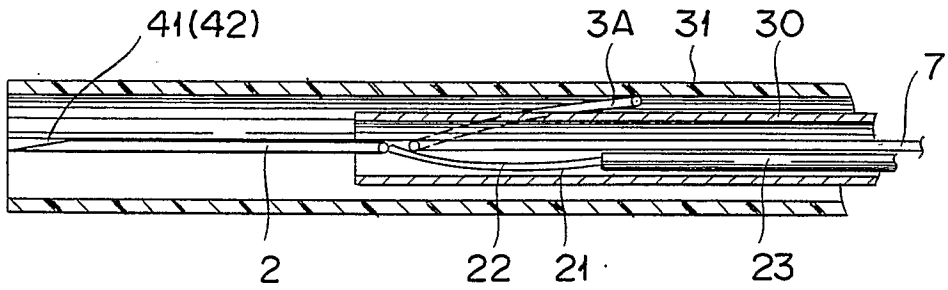


FIG.8

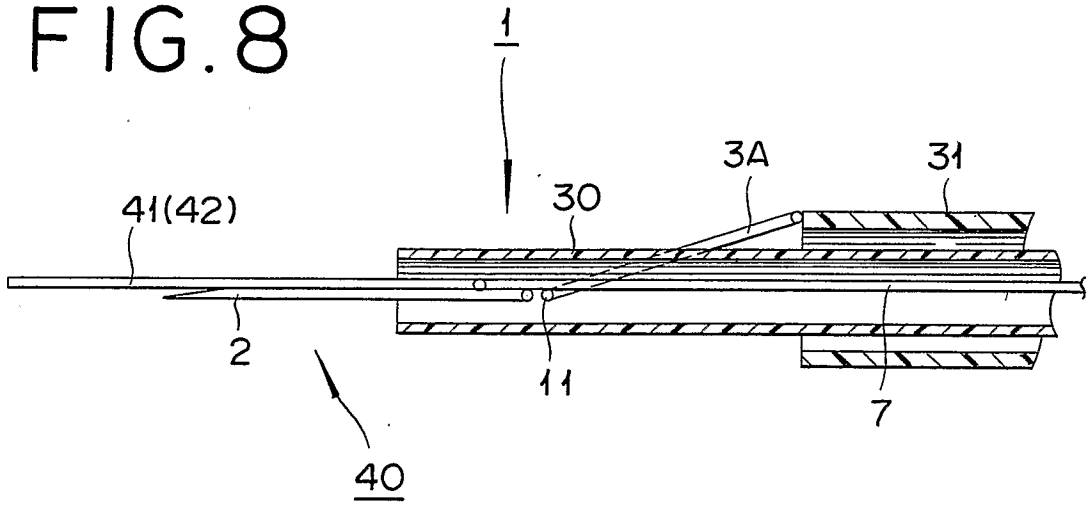


FIG.9

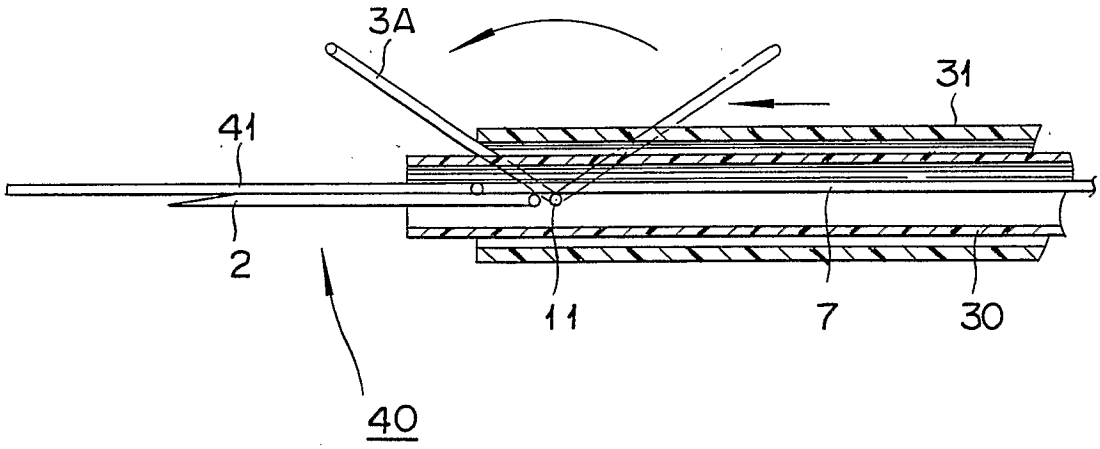


FIG. 10

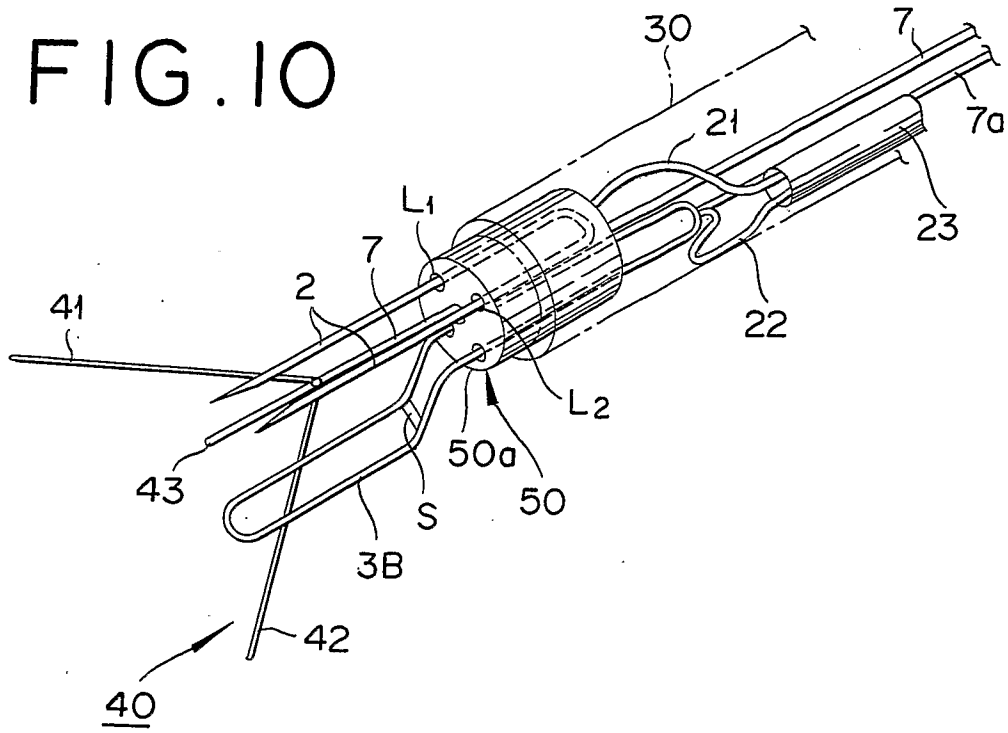

30
7
7a
21
23
L1
7
2
41
22
L2
50a
50
43
S
3B
42
40

FIG. 11

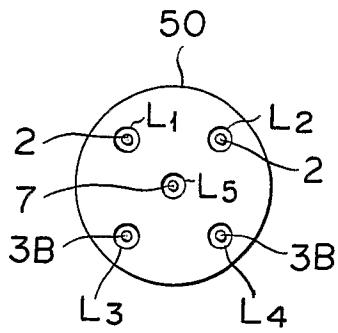

50
L1
L2
2
2
7
L5
3B
3B
L3
L4

FIG. 12

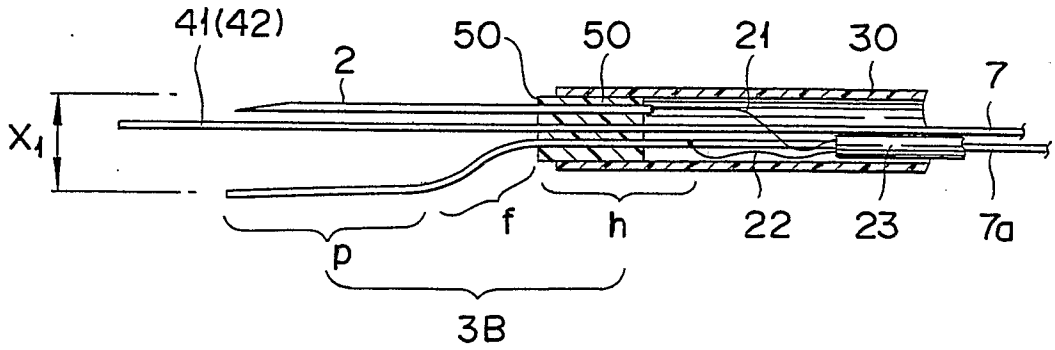


FIG. 13

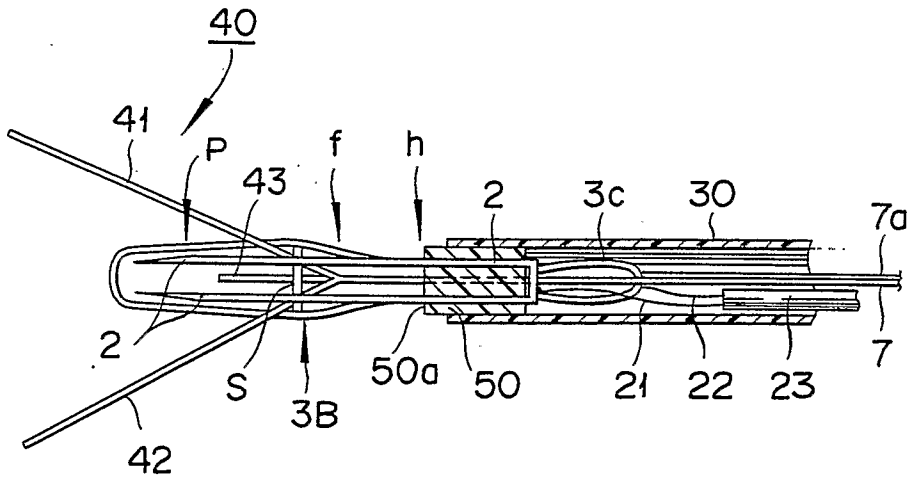


FIG. 14

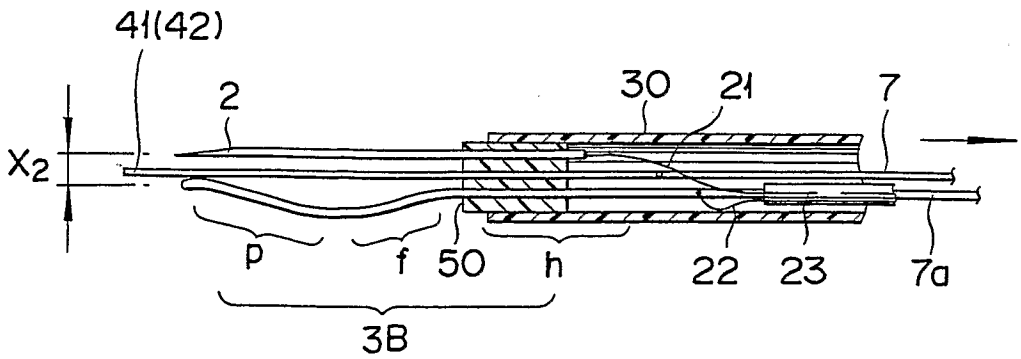


FIG. 15

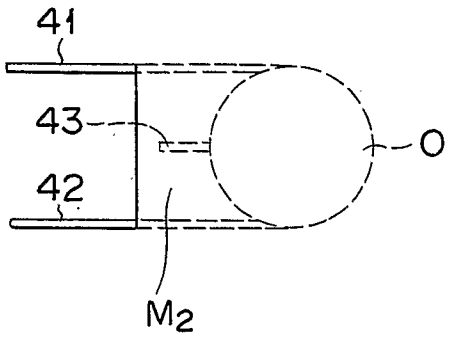


FIG. 16A

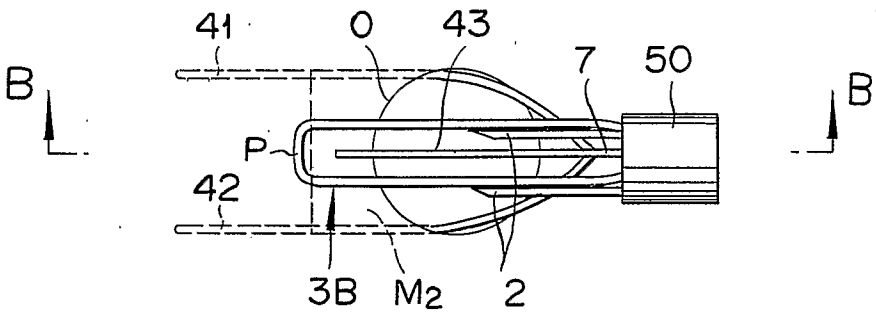


FIG. 16B

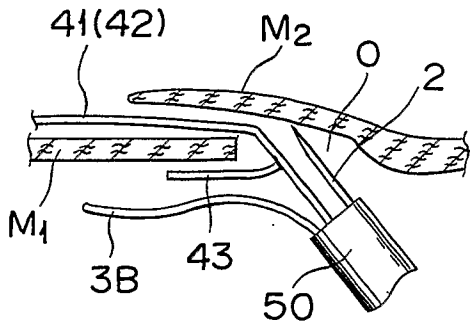


FIG. 17

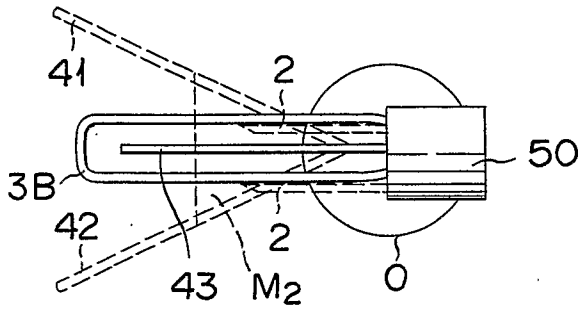


FIG. 18

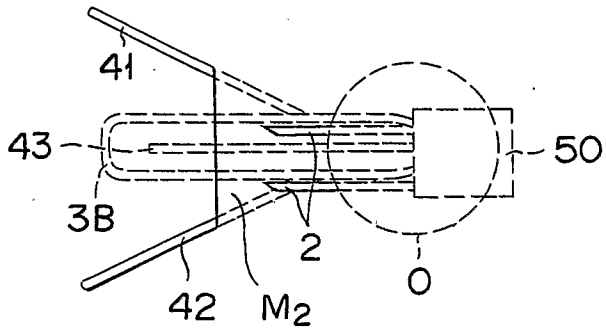


FIG. 19

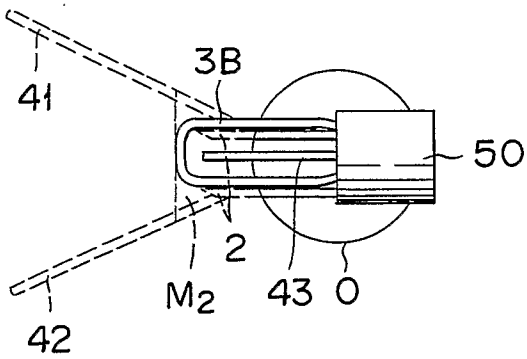


FIG. 20

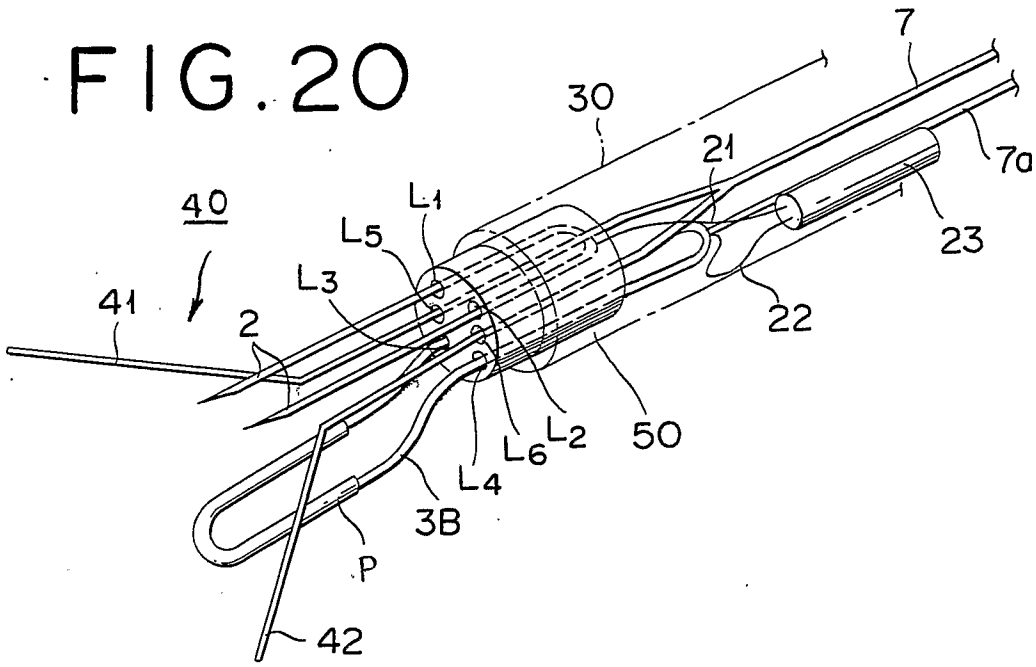


FIG. 21

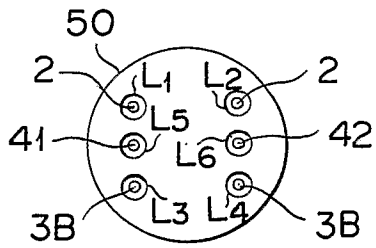


FIG. 22

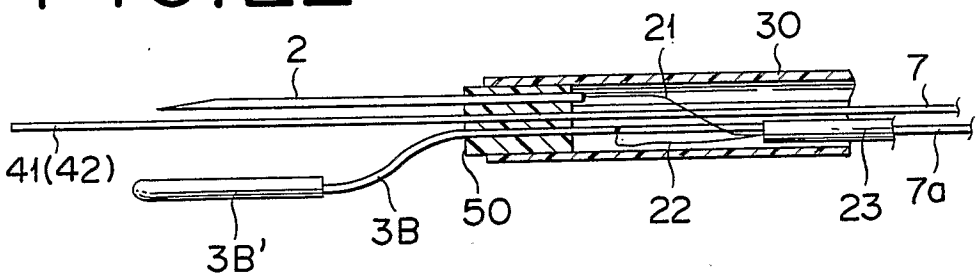


FIG. 23

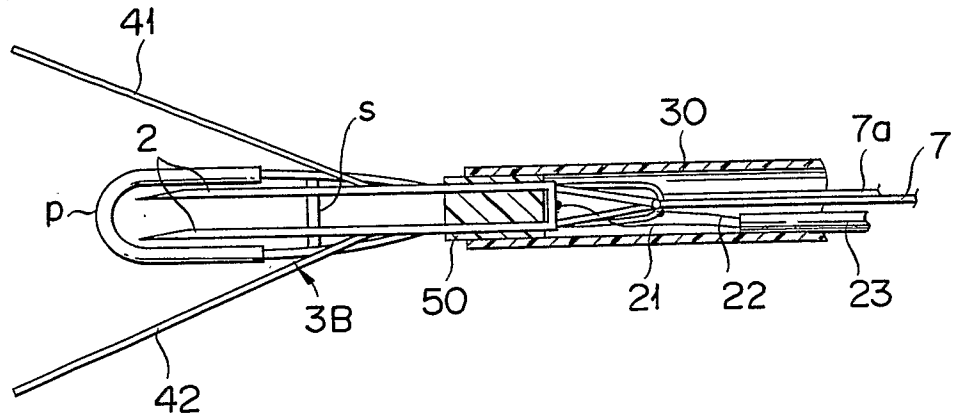
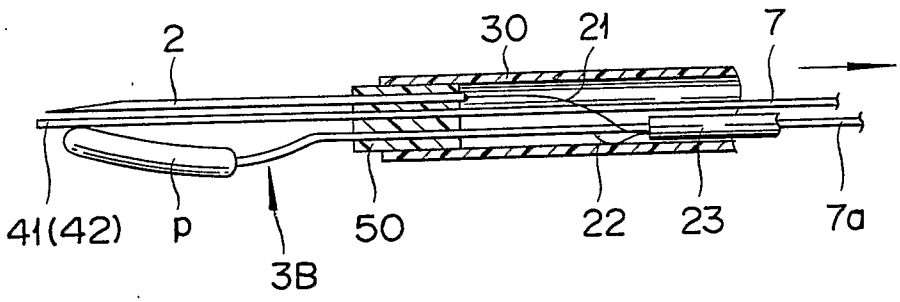


FIG. 24



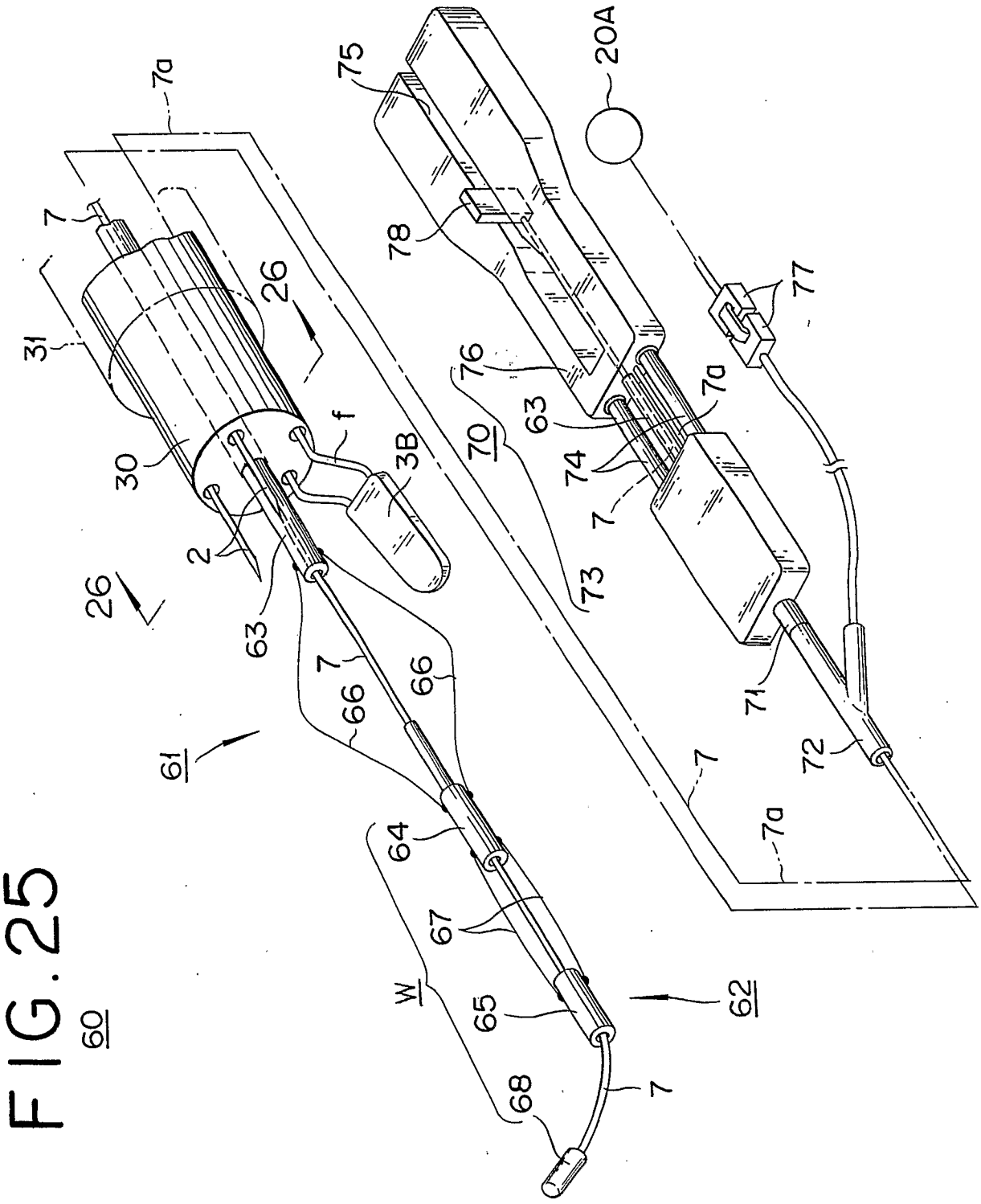

7a
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FIG. 25

60

FIG. 26

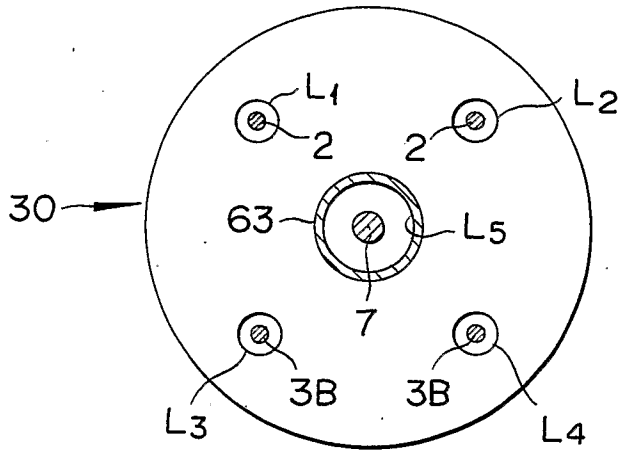

FIG. 27

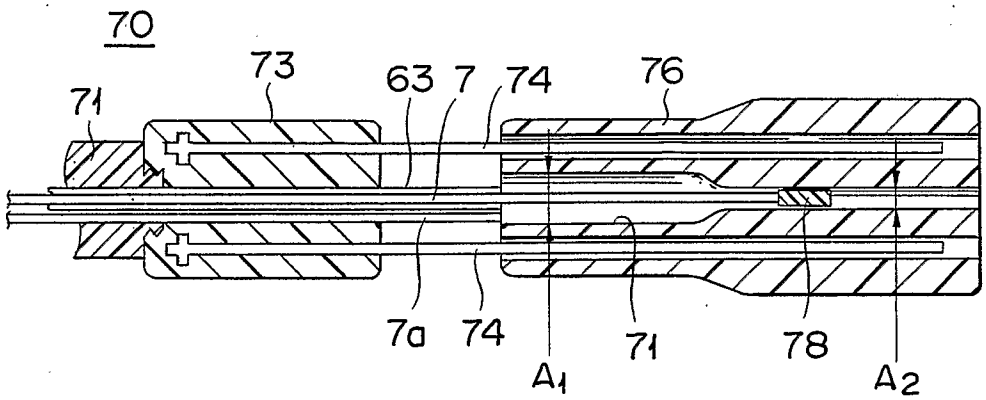

FIG. 28A

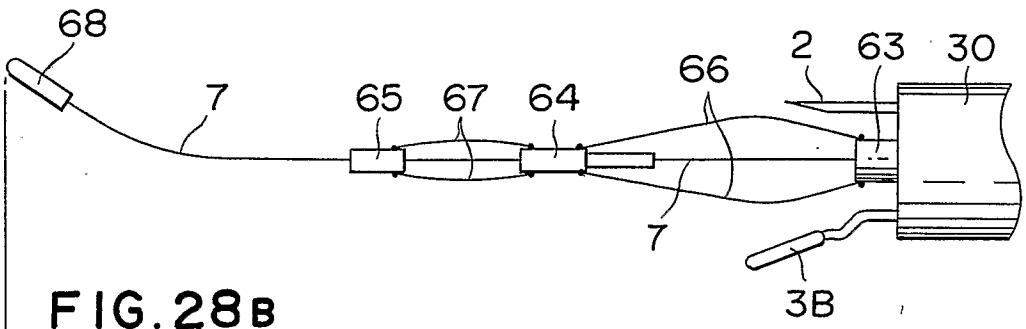

FIG. 28B

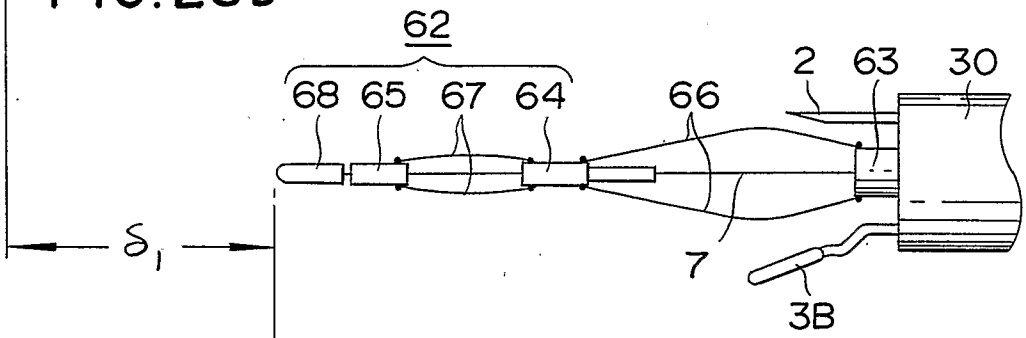

FIG. 28C

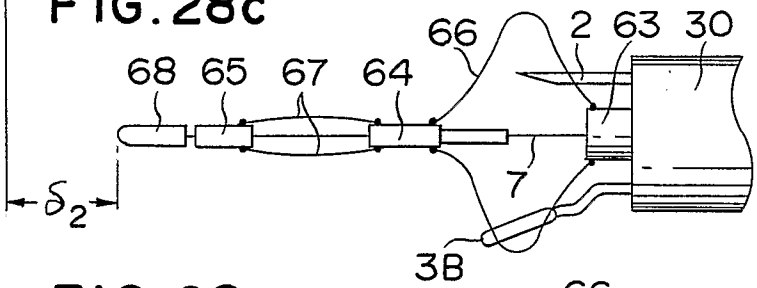

FIG. 28D

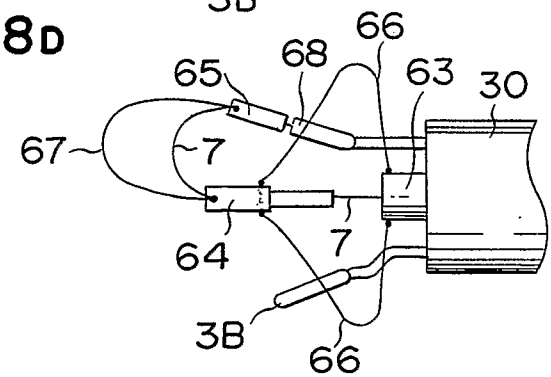

FIG. 29

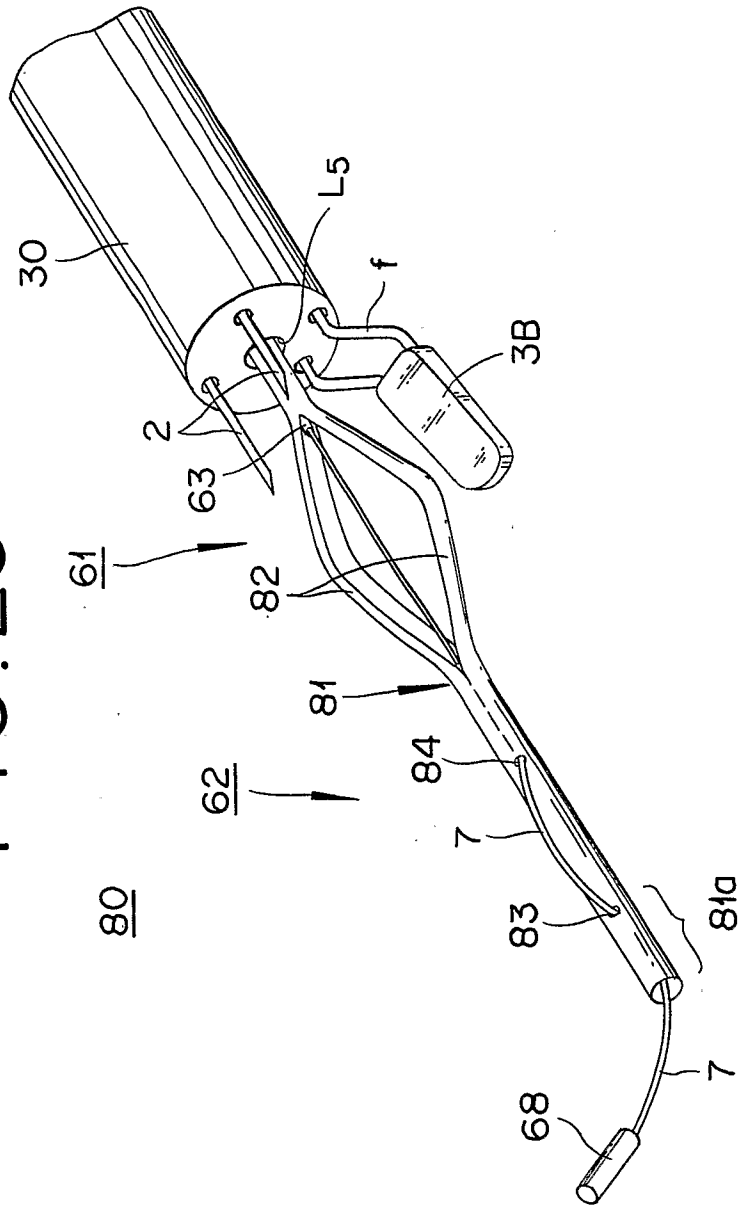

FIG. 30

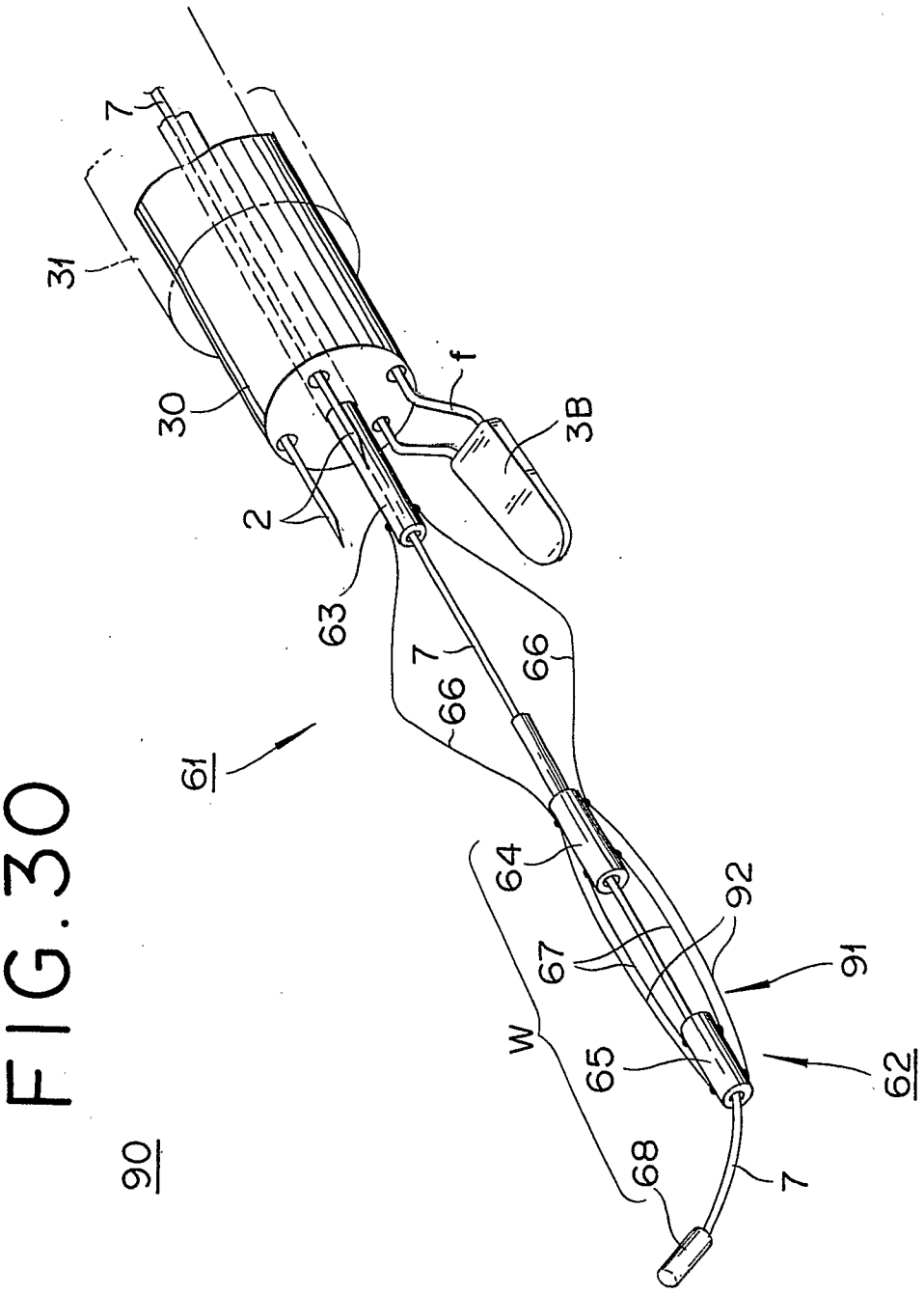

FIG.31

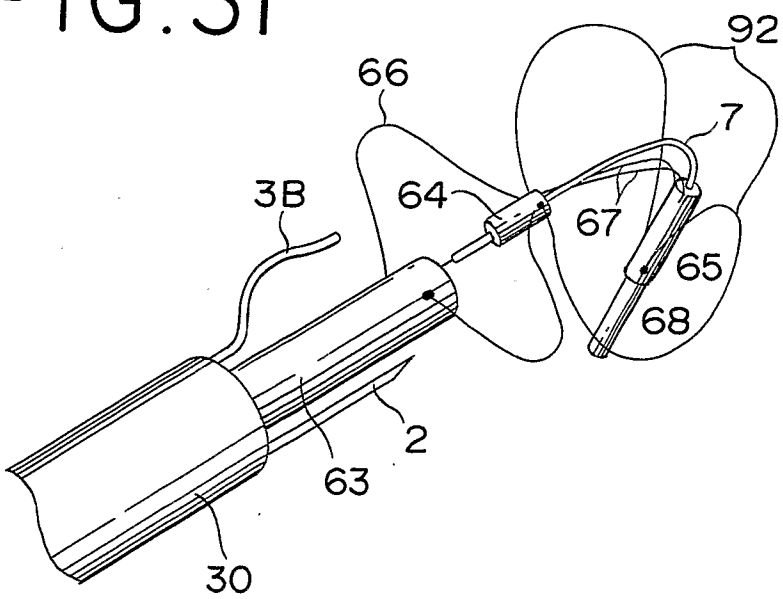
92
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FIG.32

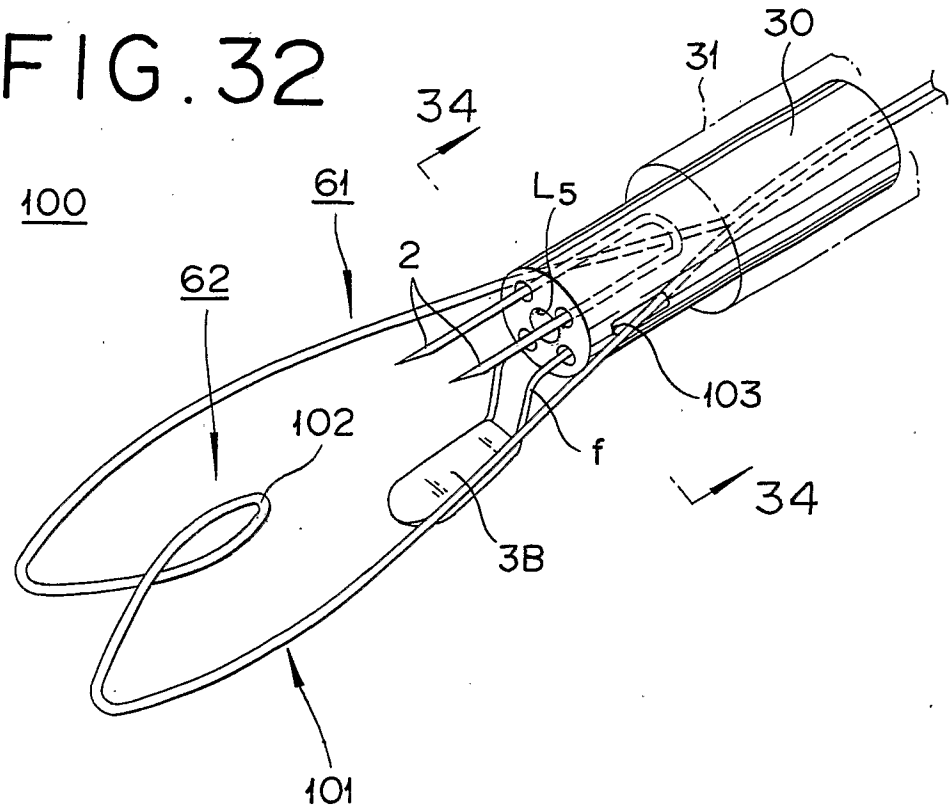
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FIG.33

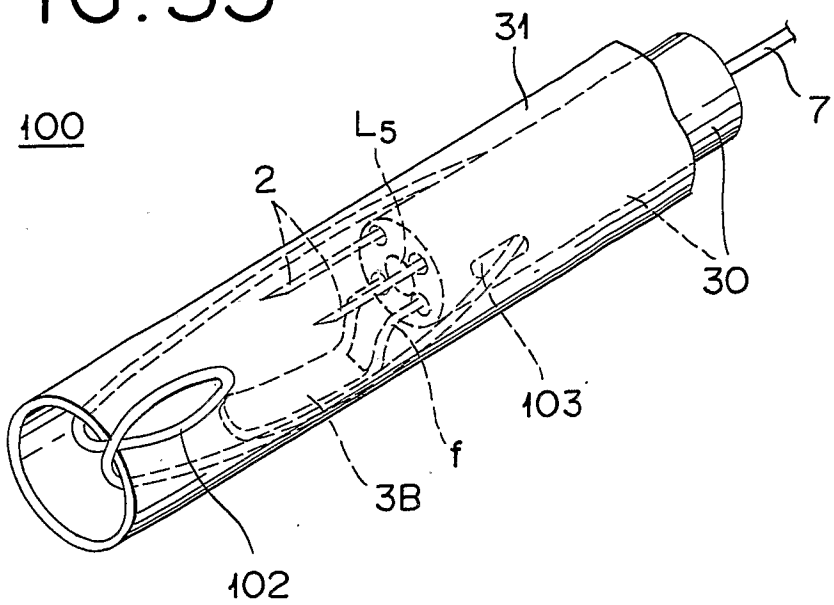
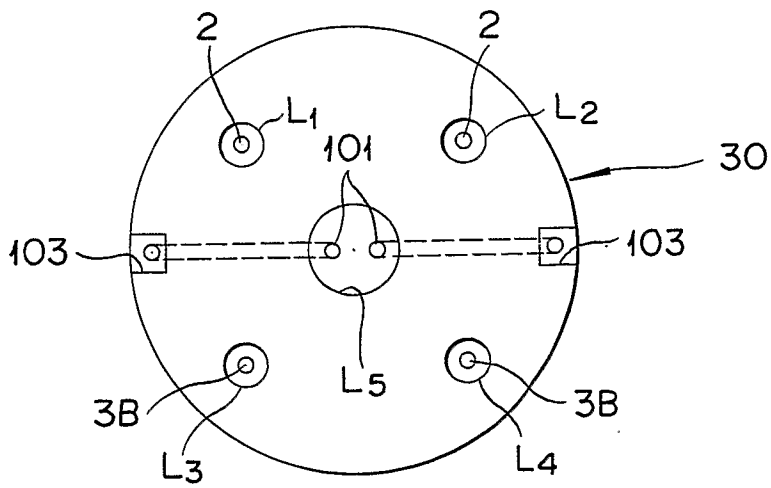


FIG.34



INTERNATIONAL SEARCH REPORT

International application No
PCT/JP2007/053977

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B18/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/086944 A (CIERRA INC [US]; MALECKI WILLIAM [US]; FRANCIS DAN [US]; HORNE KENNETH) 14 October 2004 (2004-10-14) cited in the application	1,2,4, 8-13,21, 23-25
Y	paragraphs [0065], [0080], [0083], [0086]; figures 3,10,12,13,15	3,6,7
X,P	WO 2006/110830 A (CIERRA INC [US]; ALEJANDRO JOSE [US]; ENGELSON ERIK [US]; FILLOUX DOMI) 19 October 2006 (2006-10-19) paragraph [0168]; figure 39	1
Y	US 2003/144652 A1 (BAKER JAMES A [US] ET AL) 31 July 2003 (2003-07-31) paragraph [0039]; figure 1	3

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
15 June 2007	22/06/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	MAYER-MARTENSON, E

INTERNATIONAL SEARCH REPORT

International application No
PCT/JP2007/053977

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2004/068274 A1 (HOOVEN MICHAEL D [US]) 8 April 2004 (2004-04-08) paragraphs [0015], [0059]; figure 9	6,7
A	US 2004/243122 A1 (AUTH DAVID C [US] ET AL) 2 December 2004 (2004-12-02) paragraph [0049]; figure 5	1
A	US 6 102 926 A (TARTAGLIA JOSEPH M [US] ET AL) 15 August 2000 (2000-08-15) figures 15A-16B	8-20

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