

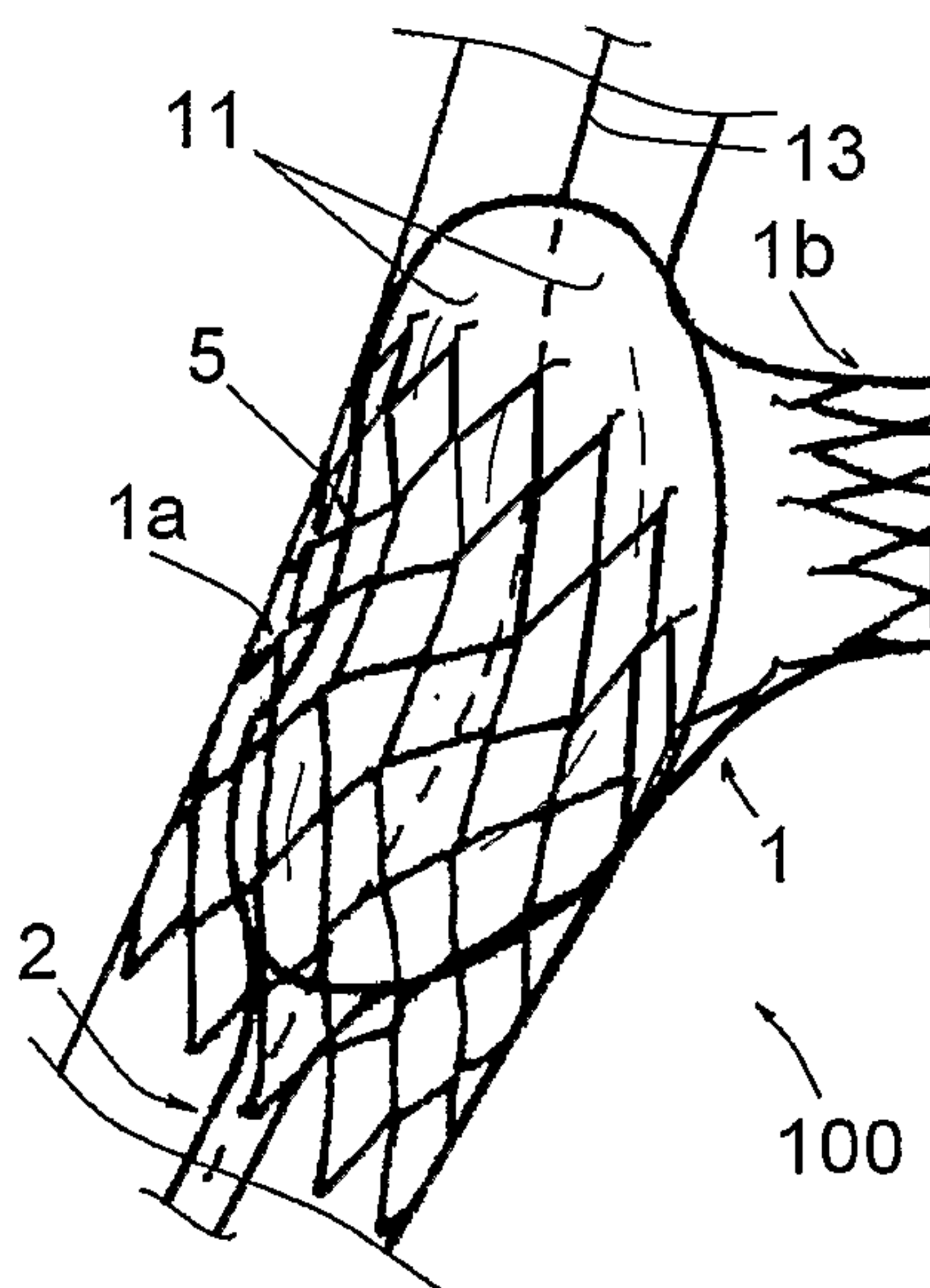


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(54) Title: DEVICE ALLOWING THE TREATMENT OF BODILY CONDUITS AT AN AREA OF A BIFURCATION



(57) **Abrégé/Abstract:**

The device comprises a stent (1) and a separating means (11), the stent (1) having a number of areas of separation (8) and the separating means (11) being able to be introduced through the wall of the stent (1) at an area of separation (8). According to embodiments of the invention, - each area of separation (8) has a number of separable junctions (6); - the activation of the separating means (11) separates at least one of the separable junctions (6) of said area of separation (8) so as to separate the stent (1) into two stent sections (1a, 1b) at the area of the bifurcation (100) and to allow the stent sections (1a, 1b) to further expand to respectively conform to a shape of the main conduit (102) and to a shape of the secondary conduit (103) at the area of the bifurcation (103).

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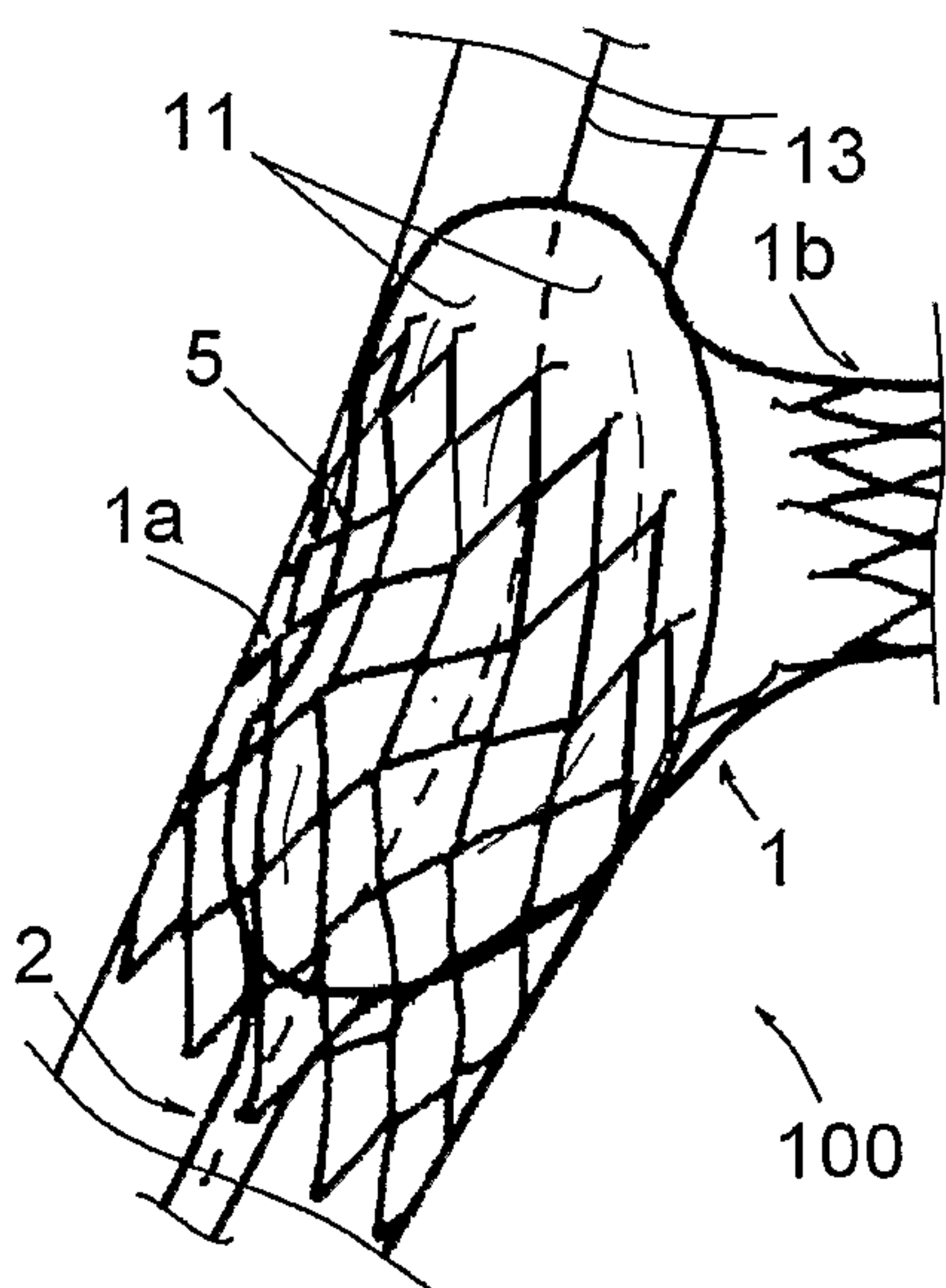
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(54) Title: DEVICE ALLOWING THE TREATMENT OF BODILY CONDUITS AT AN AREA OF A BIFURCATION



(57) Abstract: The device comprises a stent (1) and a separating means (11), the stent (1) having a number of areas of separation (8) and the separating means (11) being able to be introduced through the wall of the stent (1) at an area of separation (8). According to embodiments of the invention, - each area of separation (8) has a number of separable junctions (6); - the activation of the separating means (11) separates at least one of the separable junctions (6) of said area of separation (8) so as to separate the stent (1) into two stent sections (1a, 1b) at the area of the bifurcation (100) and to allow the stent sections (1a, 1b) to further expand to respectively conform to a shape of the main conduit (102) and to a shape of the secondary conduit (103) at the area of the bifurcation (103).

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DEVICE ALLOWING THE TREATMENT OF BODILY CONDUITS AT AN AREA OF A BIFURCATION

FIELD OF THE INVENTION

The present invention relates to a device allowing the treatment of bodily
5 conduits at an area of a bifurcation; that is, at an area of the separation of a
main conduit into two secondary conduits. It also relates to a method for
treating the bodily conduits at an area of a bifurcation, utilizing this device.

The device according to the invention may also be utilized for treating all
kinds of bifurcations, particularly vascular bifurcations.

10 BACKGROUND OF THE INVENTION

Treating stenosis of a bodily conduit by means of a radially expandable
tubular implant with a cutout or meshed structure, currently called a "stent", is
well known. This device is introduced in the unexpanded state into the conduit
to be treated up to the area of the stenosis, and is then expanded, particularly
15 by means of an inflatable balloon, or, when it has an self-expandable
structure, is released by a sheath that contains it in its contracted state.

In particular, the use of one or two stents to treat a bifurcation is known.
In the simplest case, a single stent is implanted through the bifurcation
(method called "provisional stenting"). In more complex cases, two tubular,
20 stents are positioned according to various methods (called "T-stenting,
"culotte," "crush," etc.). These methods, that aim to hold two tubes in the
bifurcation, have the disadvantages of involving either a very significant
metallic bulk, or a partial and incomplete support of the arterial wall in the
"carina," that is, the area where the secondary conduits are connected to
25 each other. Consequently, and in all scenarios, simple tubular stents do not
provide good clinical results even if they are coated with an active molecule; in
fact, stenosis of the conduits of the bifurcation tends to reappear after several
months (restenosis), which involves a new intervention.

It is to be noted that in order to improve blood flow in the secondary duct
30 that is partially obstructed by the stent, the practitioner may introduce a
balloon through a mesh of the stent in order to enlarge this mesh. This
enlargement is limited by the perimeter of the mesh, which has a smaller

diameter than the arterial section in the bifurcation, and therefore does not allow a sufficient opening to be offered.

EP 1 034 751 A2 discloses a balloon expandable stent capable of reducing the degree of inhibition of a blood stream to a branched blood vessel. In the stent, connection portions between adjacent wavy annular members are weaker than other parts and can be broken. In use, the stent may be placed in a blood vessel passing a side branch, and dilated. A balloon may then be inserted through the side wall of the already-dilated stent at the opening to the side branch and inflated, as shown in Fig. 18. As a result, while the stent dilation does not change, connection portions adjacent the balloon are broken to form a hole in the stent side wall almost equal to the inflated diameter of the balloon. Because of the plastic nature of the stent material, the hole remains open, facilitating flow through the side branch. This stent is intended to be used in T-bifurcations, i.e. where the main conduit is straight and the side branch has a much smaller diameter than the main the conduit.

Stents called "dedicated" stents for treating a bifurcation are known from, for example, documents WO 2005/1094728, WO 01/174273 or US 6 210 429. In general they have a special feature of having an opening in a portion of the stent in order to allow communication with the secondary conduit without disturbing the blood flow. However, this previously made, single opening necessitates that the stent be placed very precisely longitudinally and angularly in the bifurcation. Different means are provided to facilitate this placement, such as a second guide or a second balloon, but their utilization makes the implantation procedure complex and long, and the placement remains especially uncertain.

Providing a stent in at least two partially separated parts, wherein one, in a truncated form, is designed to be placed in the main conduit, and wherein at least one other, in a cylindrical form, is designed to be placed in a secondary conduit, is known from documents EP 0 909 147 or WO 2004/017865.

However, treatment of a bifurcation with such stents remains a relatively long operation that is difficult and delicate to carry out, particularly considering the necessary precise position of the stent in the bifurcation.

Documents US 6 258 117 or EP 1 290 987 describe stents comprising a plurality of connection structures delimiting portions of the stent between them,

these connection structures allow different portions of the stent to be separated after implantation. Said stent portions, therefore released from each other after implantation, allow a better adaptation of the stent to the shape of the bodily conduit treated.

5 These stents are not adapted to the treatment of a bifurcation and do not solve the aforementioned disadvantage connected to such treatment.

OBJECTS OF THE INVENTION

10 The object of the present invention is to provide a device allowing said disadvantage to be solved, that is, allowing a bifurcation to be treated in a relatively easy, quick and simple-to-achieve manner, by allowing the creation of a support adapted to the shapes of both conduits.

SUMMARY OF THE INVENTION

15 The device comprises a stent and a separating means, the stent having a number of areas of separation and the separating means being able to be introduced through the wall of the stent at an area of separation and to exert a separating force,

wherein:

20 - the stent is a self-expanding stent having two states of expansion, a first one in which the stent has a first cross-section area and a second one in which the stent has a second cross-section area, larger than said first cross-section area;

25 - each area of separation have a number of separable junctions, by which the medial portion of the sent is maintained in the first state of expansion when the ends of the stent are maintained in this first state of expansion;

30 - the separating force provided by the separating means separates at least one of the separable junctions of said area of separation so as to separate the self-expanded stent into two stent sections at the area of the bifurcation and to allow at least one of the stent sections to further self-expand until said second state of expansion, in which said at least one stent section conforms to a shape of the main conduit and/or to a shape of the secondary conduit at the area of bifurcation.

The separable junctions are preferably relatively weak junctions, which are breakable under the separating force of the separating means but which are designed so that they do not separate as a result of normal bodily stresses on the stent.

5 Said relatively weak portions are preferably provided in a regular annular arrangement around the stent.

A plurality of said areas of separation is preferably provided longitudinally along the stent.

10 Therefore, with the device according to the invention, the stent is brought to the level of the bifurcation to be treated, is disposed in the bifurcation in such a manner as to be extended both in the principal duct and in one of the secondary ducts, and is expanded at said first state of expansion; the plurality of areas of separation allows a leeway in the longitudinal positioning of the stent in the bifurcation and in choosing the area of separation to be separated;
15 said separating means is then engaged through the wall of the stent, at the level of the area of separation that appears to be the most optimal to make an opening in the stent (generally this will be closest to the "carena," that is, the area at the level of which the two secondary ducts are joined near the bifurcation); the separating means is then brought to exert said separating
20 force, in order to separate at least one of the separable junctions of this area of separation, and, doing this, to individualize the two parts of the stent, one extending in the principal duct up to the "carena" and the other extending in the secondary duct; the part extending in the principal duct up to the "carena" then expands in the bifurcation until said second state of expansion. It can
25 expand on its own or possibly, but not necessarily, be further expanded by an expansion means such as a balloon.

Positioning of the stent according to the invention involves fewer operations, or may be done by a technique that is easier to implement than existing techniques. The aforementioned leeway in the longitudinal positioning
30 of the stent in the bifurcation and in the choice concerning the area of separation at the level of which the lateral opening of the stent is made are advantageous.

Said areas of separation may be perpendicular to the longitudinal axis of the stent, or may be more or less oblique with relation to the stent. Preferably,

said areas of separation are rectilinear, or not rectilinear, for example chevron shaped.

The stent preferably has a structure which has, in said second state of expansion, a cross-sectional area which is at least 125%, for example 200%
5 or more, 300% or more, 400% or more or even 500% or more, more than the cross-sectional area of the stent in said first state of expansion. When the main conduit has a frustoconical shape in the area of the bifurcation, the stent has therefore an unconstrained fully expanded cross-sectional area of at least
10 125% more than a cross-sectional area of the main conduit at a narrower end of the frustoconical shape.

Preferably, means are provided to ensure the engagement of the separating means through said area of separation. This means may, for example, comprise:

- means for marking each area of separation, particularly in the form of
15 radio-opaque markers; and/or
- a distinctive structure of the portions of the stent situated on each side of said area of separation defining open cells near each area of separation.

Such means may help ensure that the separating means is engaged at the level of an area of separation and not through possible meshes or closed
20 cells that may comprise inseparable portions of the stent; for example a more open mesh structure of the stent portions at an area of separation avoid the risk of inserting the separating means outside of an area of separation.

Each separable junction may, for example, be in the form of a bridge connected to adjacent stent portions. At least one bridge may also comprise
25 one or more weak portions designed to be broken, for example in the form of one or more thinnings of the bridge section, in the form of cuts or perforations, particularly circular, provided in this bridge, in the form of one or more grooved or striated areas, in the form of two parts forming interconnected hooks, specific for being deformed for separating under the action of the separating
30 means, or in the form of a microlever type microelectromechanical system (called "MEMS"), particularly specific for being opened with the help of a cryotherapy balloon cooling these microlevers.

Methods of treating a bifurcation according to the invention comprise the following steps:

a. inserting a self-expanding stent through a conduit into the area of bifurcation and locating the stent partially in the main conduit and partially in a secondary conduit;

b. allowing the stent to self-expand; and

5 c. at least partially separating the self-expanded stent into two stent sections at the area of bifurcation and allowing the stent sections to further self-expand to respectively conform to a shape of the main conduit and to a shape of the secondary conduit at the area of bifurcation.

10 Preferably, the step a. comprises bending the stent at least 10 degrees, for example at least 10, 15, 20, 30 or 40 degrees, between the main conduit and the secondary conduit.

Preferably, the area of bifurcation has a Y-shape where the main conduit divides into two said secondary conduits.

15 Preferably, the area of bifurcation has a T-shape and step a. comprises bending the stent around a juncture between a stem and a cross piece of the T-shape.

Preferably, the step c. comprises allowing the stent section that remains in the main conduit to expand to conform to and support a frustoconical shape of the main conduit at the area of bifurcation.

20 Preferably, the step c. comprises breaking the stent sections at relatively weak portions of a wall of the stent.

Preferably, said relatively weak portions are provided in a regular annular arrangement around the stent.

25 Preferably, a plurality of said annular arrangements around the stent are provided longitudinally along the stent.

Preferably, said relatively weak portions of a wall of the stent do not separate as a result of normal bodily stresses on the stent.

Preferably, the step c. comprises completely separating the stent into two detached sections.

30 Preferably, the step c. comprises only partially separating the stent into two attached sections.

Preferably, said stent is separated around at least 20% of its circumference.

Preferably, the step c. comprises inserting a separating means through a wall of said stent and expanding said separating means to separate said stent into said two sections.

5 Preferably, the main conduit has an expanding frustoconical shape in the area of bifurcation, and said method further comprises selecting as said stent a stent with an unconstrained fully expanded cross-sectional area of at least at least 125%, for example 200% or more, 300% or more, 400% or more or even 500% or more, more than a cross-sectional area of the main conduit at a narrower end of the frustoconical shape.

10 Methods of treating a bifurcation according to the invention comprise the following steps:

a. inserting a stent through said lumen into the area of bifurcation and locating the stent partially in the main conduit and partially in a said secondary conduit with a bend in the stent of at least 10 degrees, for example
15 at least 10, 15, 20, 30 or 40 degrees, between the main conduit and the secondary conduit;

b. causing the stent to expand; and

c. at least partially separating the expanded stent into two stent sections at the area of bifurcation and causing the stent sections to further
20 expand to respectively conform to a shape of the main conduit and to a shape of the secondary conduit at the area of bifurcation.

Preferably, said stent is a self-expandable stent, and the stent is caused to expand in step b. by releasing the stent from a constraint against self-expansion.

25 Preferably, said stent is a self-expandable stent, and the stent is caused to expand in step c. by the act of separating the stent into two sections and thereby releasing newly separated ends of the stent sections to self-expand.

Preferably, the step c. comprises causing the stent section that remains in the main conduit to expand to conform to and support a frustoconical shape
30 of the main conduit at the area of bifurcation.

Preferably, the step c. comprises breaking the stent sections at relatively weak portions of a wall of the stent.

Preferably, said relatively weak portions of a wall of the stent do not separate as a result of normal bodily stresses on the stent.

Preferably, the step c. comprises completely separating the stent into two detached sections.

Preferably, the step c. comprises only partially separating the stent into two attached sections.

5 Preferably, said stent is separated around at least 20%, for example at least 25% or 30%, of its circumference.

Preferably, the step c. comprises inserting a separating means through a wall of said stent and expanding said separating means to break said stent into said sections.

10 Preferably, the main conduit has an expanding frustoconical shape in the area of bifurcation, and said method further comprises selecting as said stent a stent with an unconstrained fully expanded cross-sectional area at least 125%, for example 200% or more, 300% or more, 400% or more or even 500% or more, more than a cross-sectional area of the main conduit at a
15 narrower end of the frustoconical shape.

DESCRIPTION OF THE FIGURES

Figure 1 is a side view of a portion of a stent of the invention; in this view, only the structures situated in the foreground are represented, for clarity of the drawing;

20 Figure 2 is a detail view, at a very enlarged scale, of the stent of Figure 1;

Figure 3 is a view of a stent that is similar to the stent of Figure 1, after the lateral opening of the stent by separation of separable bridges that comprise this stent;

25 Figure 4 is a view of a balloon catheter that may be utilized to expand the stent of Figure 3;

Figure 5 is a view of the balloons of the balloon catheter of Figure 4 in transversal section, after inflation;

Figures 6 to 11 are views of different successive steps of positioning a stent at an area of a bifurcation;

30 Figures 12 and 13 are views of a stent after positioning, according to two other possible positionings of this stent in a bifurcation;

Figure 14 is a view of a longer stent after positioning in an area of two bifurcations;

Figure 15 is a view of a stent in conformance with the invention after positioning in a bifurcation in a transition area between the main conduit and the secondary conduits, the stent portion in the main conduit having a truncated conical form;

5 Figures 16 to 21 have similar views to Figure 2 of different variations of embodiment of said separable bridges;

 Figures 22 to 27 are views of different successive steps of positioning a stent at the area of a Y-shaped bifurcation.

DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

10 Figure 1 represents a radially expandable tubular implant 1, currently called a "stent," and Figure 4 represents a balloon catheter 2 allowing separation of portions of this stent 1 at the area of a bifurcation, that is, at an area of the separation of a principal bodily conduit into two secondary conduits. Stent 1 and catheter 2 form a device allowing treatment of this
15 bifurcation.

 Stent 1 in Figure 1 comprises a plurality of circular (annular) portions 5 in a cutout structure and breakable bridges 6 connecting the circular portions 5 to each other.

20 Each circular portion 5 is formed by a zigzag portion (e.g., wire) 7 whose extremities are connected to each other. The different segments 7a formed by this wire have substantially identical lengths.

 Wire 7 is in a material such that the stent 1 may pass from a radial contraction state to a radial expansion state, by deformation of the bends 7b that define the different segments 7a. The radial contraction state allows
25 engagement of the stent 1 in a sheath used to route this stent to the bifurcation to be treated, and the radial expansion state allows the stent 1 to give the bodily conduit the diameter that the conduit must have. The stent 1 may be self-expandable, that is, it may pass by itself to its radial expansion state when it is released by said routing sheath. The wire 7 may for example
30 be in a shape-memory material such as the nickel-titanium alloy known under the name "nitinol".

 Breakable bridges 6 connect the adjacent bends 7b of two consecutive circular portions 5. In the embodiment shown more particularly in Figure 2,

each of them presents a hat shape, that is, they comprise two lateral branches 6a for connection to the respective bends 7b and a curved central part 6b. Due to this shape, the bridges 6 present a certain flexibility that, in conjunction with the flexibility that the circular portions 5 themselves present, allows the stent 1 to have a certain longitudinal flexibility itself when it is in the radial expansion state, and allows for a bend of at least 10 degrees when placed in the bifurcation. Because of this longitudinal flexibility, as shown in Figure 8, a part of stent 1 may be engaged in the main conduit of a bifurcation while the other part of this stent is engaged in one of the secondary conduits of this bifurcation even when this main conduit and this secondary conduit form an angle between each other.

The rounded portion 6b of each bridge 6 of Figure 2 comprises a reduced median area 6c designed to be broken in order of priority in case of the exercise of a constraint tending to spread the two circular portions 5 apart from each other. The different reduced areas 6c of the bridges 6 situated at the same area in the longitudinal direction of the stent 1 therefore form an area 8 of relative fragility, specific for normally resisting the constraints transmitted by the bodily conduits 102, 103 in which the stent 1 is implanted but not the separation action of the two adjacent portions 5 exerted by the separation means such as a catheter balloon 2 as described below.

As shown in Figure 3, the breaking of the bridges 6 at an area 8 allows the stent 1 to be largely or completely open according to a significant portion of this area 8 in such a way as to form two independent tubular parts 1 a, 1 b that are partially separated.

With reference to Figure 4, the catheter 2 may, for example, comprise an elongated body 10, two side-by-side balloons 11 forming the separation means, and an external sliding sheath 12.

The elongated body 10 presents an axial conduit extending between the balloons 11, that allows the catheter 2 to slide on an axial guiding wire 13.

The two balloons 11 are connected to a source of inflation fluid (not represented). In the deflated state, they are maintained by the sheath 12 in a radial contraction position, represented in solid lines in Figure 4, and may be inflated until they take the form shown in interrupted lines in Figure 4 and shown in section in Figure 5. As shown in this Figure 5, each balloon 11

presents a section substantially in the shape of a "D" and is bracketed to the other balloon by its plane wall, in such a way that the two balloons 11 conjointly form a balloon having a substantially annular shape in transversal section.

5 In practice, for the treatment of a bifurcation 100 comprising atheroma plaques 101, a guiding wire 20 is first of all introduced percutaneously through the main conduit 102 and the secondary conduit 103 to be treated (see Figure 6).

10 A catheter 21 is then engaged in the main conduit 102 then the secondary conduit 103 by being guided by the wire 20, this catheter 21 comprising the stent 1 maintained in a state of radial contraction such as by an exterior sliding sheath 22; when the distal extremity of the catheter 21 is inside the secondary conduit 103, the sheath 22 may be slid in such a way as to release the stent 1, which is deployed in the secondary conduit 103 then in the
15 main conduit 102, as shown in Figures 7 and 8. This deployment allows the atheroma plaques 101 to be compressed and to consequently give the conduits 102 and 103 the adequate diameters.

The guiding wire 13 is then engaged and slides in the main conduit 102 then, through the openings that the wall of stent 1 presents, in the other
20 secondary conduit 104 of the bifurcation 100, as appears in Figure 8. This guiding wire, named a guidewire, is advantageously passed through an opening located closest to the "carena" 105, that is, the area of bifurcation 100 corresponding to the departure of the two secondary conduits 103, 104, The zigzag wire structure of portions 5 shown in Figure 8 defines only the open
25 meshes of the side of areas 8, in such a way that the practitioner is ensured of engaging the guidewire 13 between two portions 5 at area 8. The catheter 2 is then engaged on the guidewire 13 up to this portion, and the balloons 11 are engaged through the stent 1, as shown in interrupted lines in this Figure 8.

The balloons 11 are then inflated and exert on the two circular portions 5
30 between which they are engaged a constraint spreading the two portions 5 apart from each other. This inflation causes the rupture of the reduced areas 6c of the bridges 6 situated between these two circular portions 5, with the optional exception of one or more bridges 6 situated diametrically opposed to a bridge at the area of which the balloons 11 crossed stent 1 (see Figures 9

and 10), in such a way that the two tubular parts 1a, 1b are thus formed.

The balloons 11 are then deflated and the catheter 2, and the guiding wire 13, are withdrawn (see Figure 11).

5 Figures 12 and 13 show that a certain leeway in the positioning of the stent 1 in the bifurcation 100 is made possible by the existence of the plurality of areas 8 comprised of the series of bridges 6. It is therefore particularly possible to treat bifurcations 100 having different positionings of atheroma plaques 101.

10 Figure 14 shows that the stent 1 may have a long length and that it may be the subject of two or more lateral openings such as the aforementioned, one at the area of a bifurcation 100 as described above, the other(s) at the area(s) of another bifurcation(s) 110, or that two stents 1 may be positioned successively and opened laterally.

15 Figure 15 shows the case of a bifurcation presenting an area of transition that is flared between the main conduit 102 and the secondary conduits 103, 104. Part 1 a of the stent 1 may self-expand in such a way as to be adapted to this flared form of this transition area.

20 Figures 16 to 21 show that each bridge 6 may be parallel to the longitudinal axis of the stent (Figures 16 to 19) or oblique with relation to this longitudinal axis (Figures 20 and 21).

Each bridge 6 may comprise one or more areas 6c of reduced resistance, for example in the form of one or more thinnings of the section of the bridge or cuts or circular perforations provided in this bridge (Figures 16, 17, 20, 21), or of a grooved or striated area.

25 Each bridge 6 may also or alternatively, for example, comprise one or more areas 6c in a material different from the material constituting the rest of the bridge, suitable for being broken under the separation action exerted by the balloon 11 (Figure 19). Each bridge 6 may comprise two parts 6b forming interconnected hooks (Figure 18), specific for being deformed to be separated
30 under the action of separation means, or forming a microlevers-type system (called "MEMS"), specific for being opened with the help of a cryotherapy balloon to cool the microlevers.

As appearing from the aforesaid, the invention provides devices and methods allowing the treatment of bodily conduits at the area of a bifurcation

that present the decided advantage of being able to be positioned according to an operation that is shorter and less delicate to carry out than a device according to the prior art.

5 Figures 22 to 27 show different successive steps of positioning the stent at the area of a Y-shaped bifurcation. These figures are respectively showing the same steps as the Figures 6 to 11. After separation by the balloon on Figure 26, the stent continues to expand to conform to the shape of the main conduit (Figure 27). The stent clearly supports the frustoconical shape of the main conduit, which includes part of the side branch ostium.

10 It goes without saying that the invention is not limited to the embodiment described above by way of example but that it extends to all embodiments of the invention. For example, portions 5 of stent 1 may have a meshed structure; the means provided to ensure the engagement of the balloon through the selected area 8 may comprise marking means for each area 8, for
15 example in the form of radio-opaque markers; the balloon 11 may be formed from two balloons as described previously or from a single balloon; the separation means could be one or more balloons, including cryotherapy balloons, a small expansion tool, like small forceps or pliers, at the distal end of a catheter and actuated from the proximal end with wires extending in the
20 lumen of the said catheter, or other separation means; the stent can be a drug eluted stent.

CLAIMS

1 – A device allowing the treatment of bodily conduits (102, 103, 104) at the area of a bifurcation (100), the device comprising a stent (1) and a separating means (11), the stent (1) having a number of areas of separation (8) and the separating means (11) being able to be introduced through the wall of the stent (1) at an area of separation (8) and to exert a separating force;

wherein:

- the stent (1) is a self-expanding stent having two states of expansion, a first one in which the stent has a first cross-section area and a second one in which the stent has a second cross-section area, larger than said first cross-section area;

- each area of separation (8) has a number of separable junctions (6), by which the medial portion of the stent is maintained in the first state of expansion when the ends of the stent are maintained in this first state of expansion;

- the separating force provided by the separating means (11) separates at least one separable junction (6) of said area of separation (8) so as to separate the self-expanded stent (1) into two stent sections (1a, 1b) at the area of the bifurcation (100) and to allow at least one of the stent sections (1a, 1b) to further self-expand until said second state of expansion, in which said at least one stent section conforms to a shape of the main conduit (102) and/or to a shape of the secondary conduit (103) at the area of the bifurcation (103).

2 – The device according to claim 1, characterized in that the separable junctions (6) are relatively weak junctions, which are breakable under the separating force of the separating means (11) but which do not separate as a result of normal bodily stresses on the stent (1).

3 – The device according to claim 2, characterized in that said relatively weak junctions are provided in a regular annular arrangement around the stent.

4 – The device according to claim 3, characterized in that a plurality of said areas of separation (8) are provided longitudinally along the stent.

5 – The device according to claim 1, characterized in that said areas of separation are perpendicular to the longitudinal axis of the stent, or are more or less oblique with relation to the stent.

6 – The device according to claim 1, characterized in that said areas of separation are rectilinear, or not rectilinear, for example chevron shaped.

7 – The device according to claim 1, characterized in that, when the main conduit (102) has a frustoconical shape in the area of the bifurcation (100), the
5 stent (1) has a structure which has, in said second state of expansion, a cross-sectional area which is at least 125% more than the cross-sectional area of the stent (1) in said first state of expansion, so that the stent (1) has an unconstrained fully expanded cross-sectional area of at least 125% more than
10 a cross-sectional area of the main conduit (102) at a narrower end of the frustoconical shape.

8 – The device according to claim 1, characterized in that means (7) are provided to ensure the engagement of said means of separation (11) through said area of separation (8).

9 – The device according to claim 8, characterized in that said means to
15 ensure engagement comprises:

- means for marking each area of separation, particularly in the form of radio-opaque markers; and/or

- a structure of the portions of the stent situated on each side of said area of separation defining open cells near each area of separation.

10 – The device according to claim 1, characterized in that each
20 separable junction (6) is in the form of a bridge connected to the adjacent stent portions.

11 – The device according to claim 10, characterized in that at least one
25 said bridge comprises one or more weak portions designed to be broken, particularly in the form of one or more thinnings of the bridge section, in the form of cuts or perforations, particularly circular, provided in this bridge, in the form of one or more grooved or striated areas, in the form of two parts forming interconnected hooks, specific for being deformed for separating under the action of the separating means, or in the form of a microlever type
30 microelectromechanical system (called "MEMS"), particularly specific for being opened with the help of a cryotherapy separating means cooling these microlevers.

12 – A method of treating bodily conduits at an area of a bifurcation (100), comprising the following steps:

a. inserting a self-expanding stent (1) through a conduit into the area of bifurcation (100) and locating the stent (1) partially in a main conduit (102) and partially in a secondary conduit (103);

b. allowing the stent (1) to self-expand; and

5 c. at least partially separating the self-expanded stent (1) into two stent sections (1a, 1b) at an area of separation (8) of the stent at the area of the bifurcation (100) and allowing at least one of the stent sections (1a, 1b) to further self-expand to conform to a shape of the main conduit (102) and/or to a shape of the secondary conduit (103) at the area of bifurcation (100).

10 13 – A method according to claim 12, wherein step a. comprises bending the stent (1) at least 10 degrees between the main conduit (102) and the secondary conduit (103).

14 – A method according to claim 12, wherein the area of bifurcation has a Y-shape where the main conduit divides into two said secondary conduits.

15 15 – A method according to claim 12, wherein the area of bifurcation has a T-shape and step a. comprises bending the stent around a juncture between a stem and a cross piece of the T-shape.

20 16 – A method according to claim 12, wherein step c. comprises allowing the stent section that remains in the main conduit to expand to conform to and support a frustoconical shape of the main conduit at the area of bifurcation.

17 – A method according to claim 12, wherein step c. comprises breaking the stent sections at relatively weak portions of a wall of the stent.

18 – A method according to claim 17, wherein said relatively weak portions are provided in a regular annular arrangement around the stent.

25 19 – A method according to claim 12, wherein a plurality of said areas of separation are provided longitudinally along the stent.

20 – A method according to claim 17, wherein said relatively weak portions of a wall of the stent do not separate as a result of normal bodily stresses on the stent.

30 21 – A method according to claim 12, wherein step c. comprises completely separating the stent into two detached sections.

22 – A method according to claim 12, wherein step c. comprises only partially separating the stent into two attached sections.

23 – A method according to claim 22, wherein said stent is separated around at least 20% of its circumference.

24 – A method according to claim 12, wherein step c. comprises inserting a separating means through a wall of said stent and expanding said separating means to break said stent into said two sections.

25 – A method according to claim 12, wherein the main conduit has an expanding frustoconical shape in the area of bifurcation, and said method further comprises selecting as said stent a stent with an unconstrained fully expanded cross-sectional area of at least 125% more than a cross-sectional area of the main conduit at a narrower end of the frustoconical shape.

26 – A method according to claim 12, wherein the main conduit has an expanding frustoconical shape in the area of bifurcation, and said method further comprises selecting as said stent a stent with an unconstrained fully expanded cross-sectional area of at least 300% more than a cross-sectional area of the main conduit at a narrower end of the frustoconical shape.

27 – A method according to claim 12, wherein the main conduit has an expanding frustoconical shape in the area of bifurcation, and said method further comprises selecting as said stent a stent with an unconstrained fully expanded cross-sectional area of at least 500% more than a cross-sectional area of the main conduit at a narrower end of the frustoconical shape.

28 – A method for the treatment of a bodily lumen at an area of bifurcation of said lumen where a main conduit of said lumen transitions into at least two secondary conduits, the method comprising the steps:

a. inserting a stent through said lumen into the area of bifurcation and locating the stent partially in the main conduit and partially in a said secondary conduit with a bend in the stent of at least 10 degrees between the main conduit and the secondary conduit;

b. causing the stent to expand; and

c. at least partially separating the expanded stent into two stent sections at the area of bifurcation and causing the stent sections to further expand to respectively conform to a shape of the main conduit and to a shape of the secondary conduit at the area of bifurcation.

29 – A method according to claim 28, wherein said stent is a self-expandable stent, and the stent is caused to expand in step b. by releasing the stent from a constraint against self-expansion.

5 30 – A method according to claim 28, wherein said stent is a self-expandable stent, and the stent is caused to expand in step c. by the act of separating the stent into two sections and thereby releasing newly separated ends of the stent sections to self-expand.

10 31 – A method according to claim 28, wherein step c. comprises causing the stent section that remains in the main conduit to expand to conform to and support a frustoconical shape of the main conduit at the area of bifurcation.

32 – A method according to claim 28, wherein step c. comprises breaking the stent sections at relatively weak portions of a wall of the stent.

15 33 – A method according to claim 32, wherein said relatively weak portions of a wall of the stent do not separate as a result of normal bodily stresses on the stent.

34 – A method according to claim 28, wherein step c. comprises completely separating the stent into two detached sections.

35 – A method according to claim 28, wherein step c. comprises only partially separating the stent into two attached sections.

20 36 – A method according to claim 28, wherein said stent is separated around at least 20% of its circumference.

37 – A method according to claim 28, wherein step c. comprises inserting a separating means through a wall of said stent and expanding said separating means to break said stent into said sections.

25 38 – A method according to claim 28, wherein the main conduit has an expanding frustoconical shape in the area of bifurcation, and said method further comprises selecting as said stent a stent with an unconstrained fully expanded cross-sectional area of at least 125% more than a cross-sectional area of the main conduit at a narrower end of the frustoconical shape.

30 39 – A method according to claim 28, wherein the main conduit has an expanding frustoconical shape in the area of bifurcation, and said method further comprises selecting as said stent a stent with an unconstrained fully expanded cross-sectional area of at least 300% more than a cross-sectional area of the main conduit at a narrower end of the frustoconical shape.

40 – A method according to claim 28, wherein the main conduit has an expanding frustoconical shape in the area of bifurcation, and said method further comprises selecting as said stent a stent with an unconstrained fully expanded cross-sectional area of at least 500% more than a cross-sectional
5 area of the main conduit at a narrower end of the frustoconical shape.

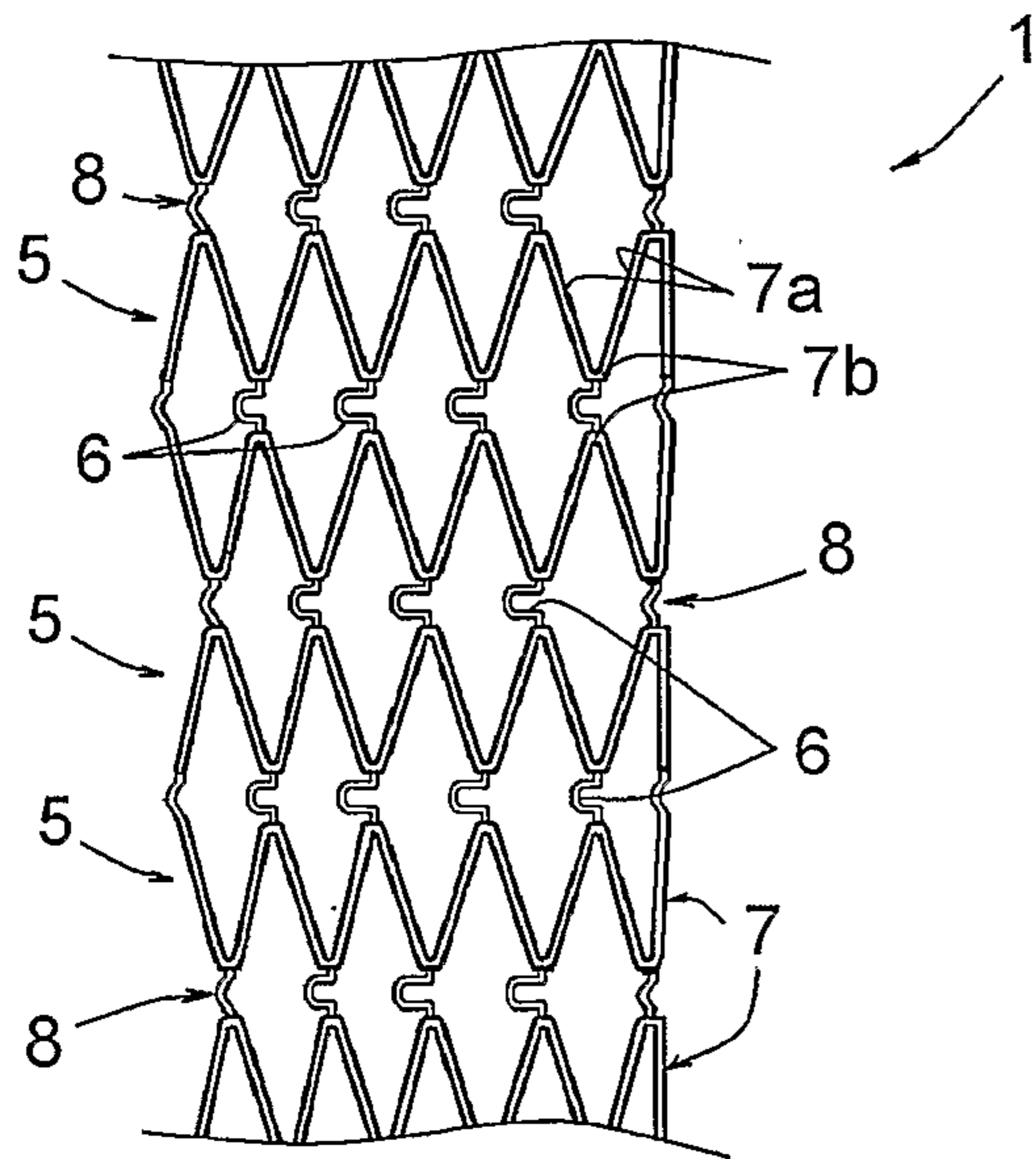


FIG. 1

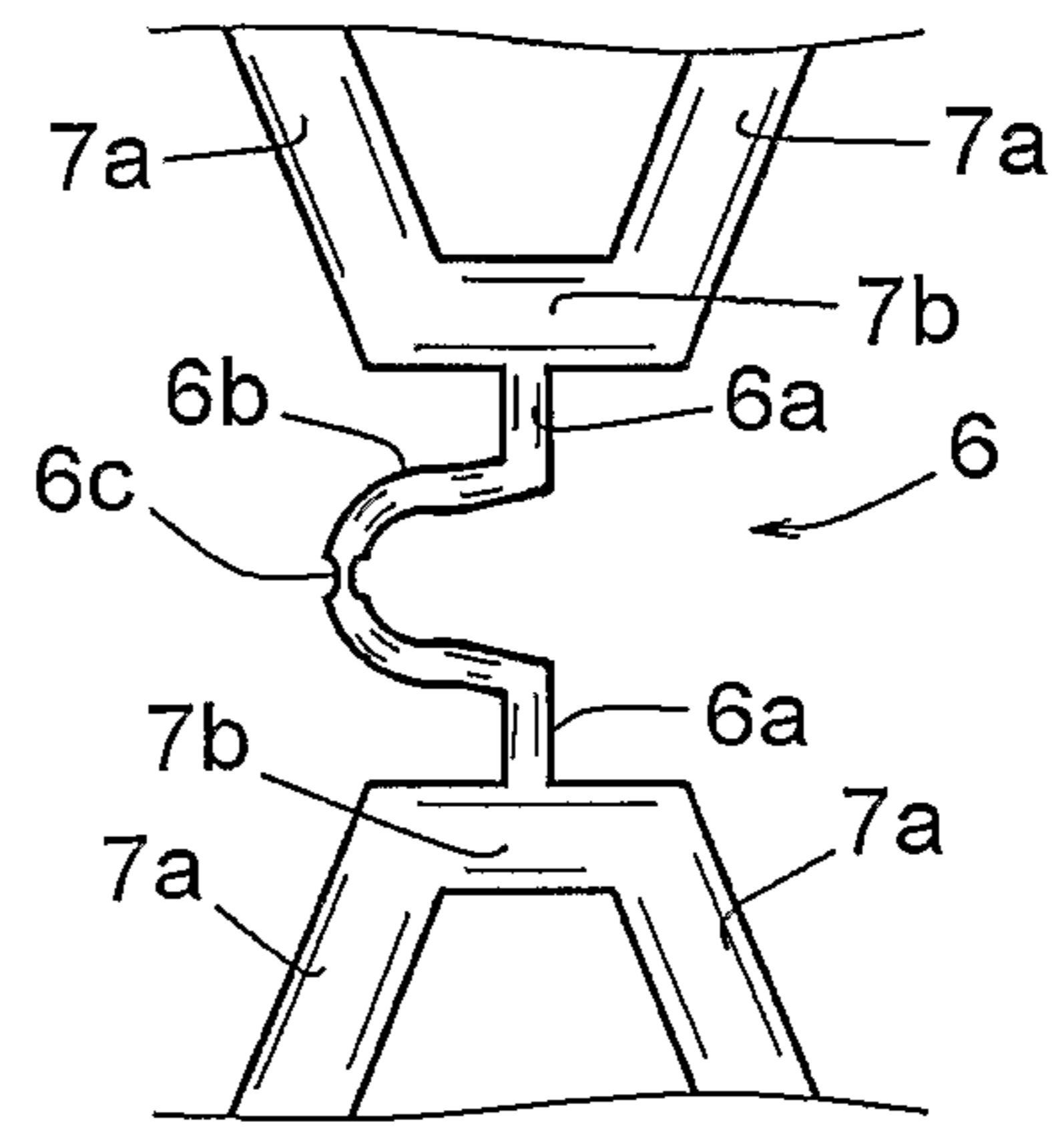


FIG. 2

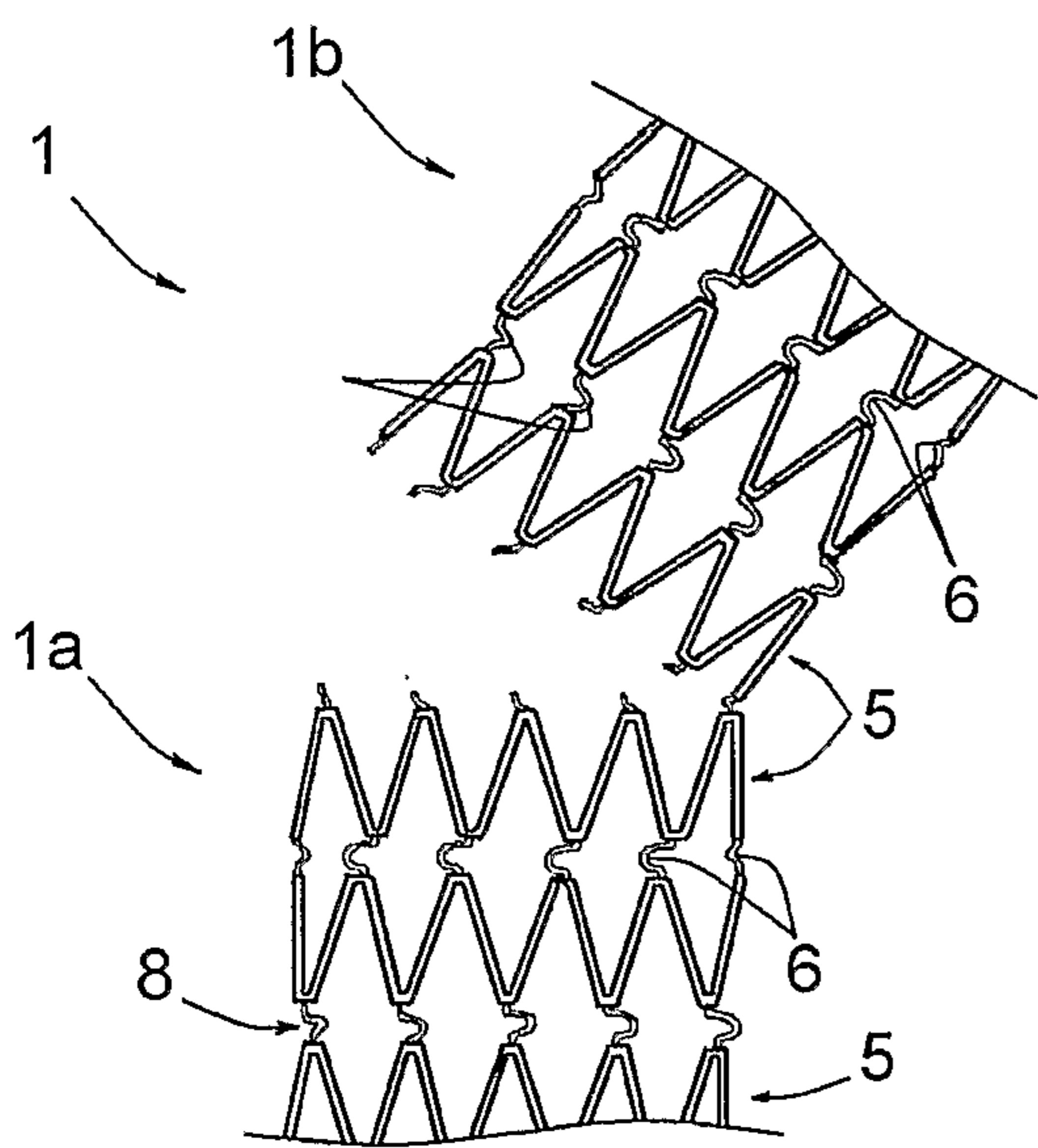


FIG. 3

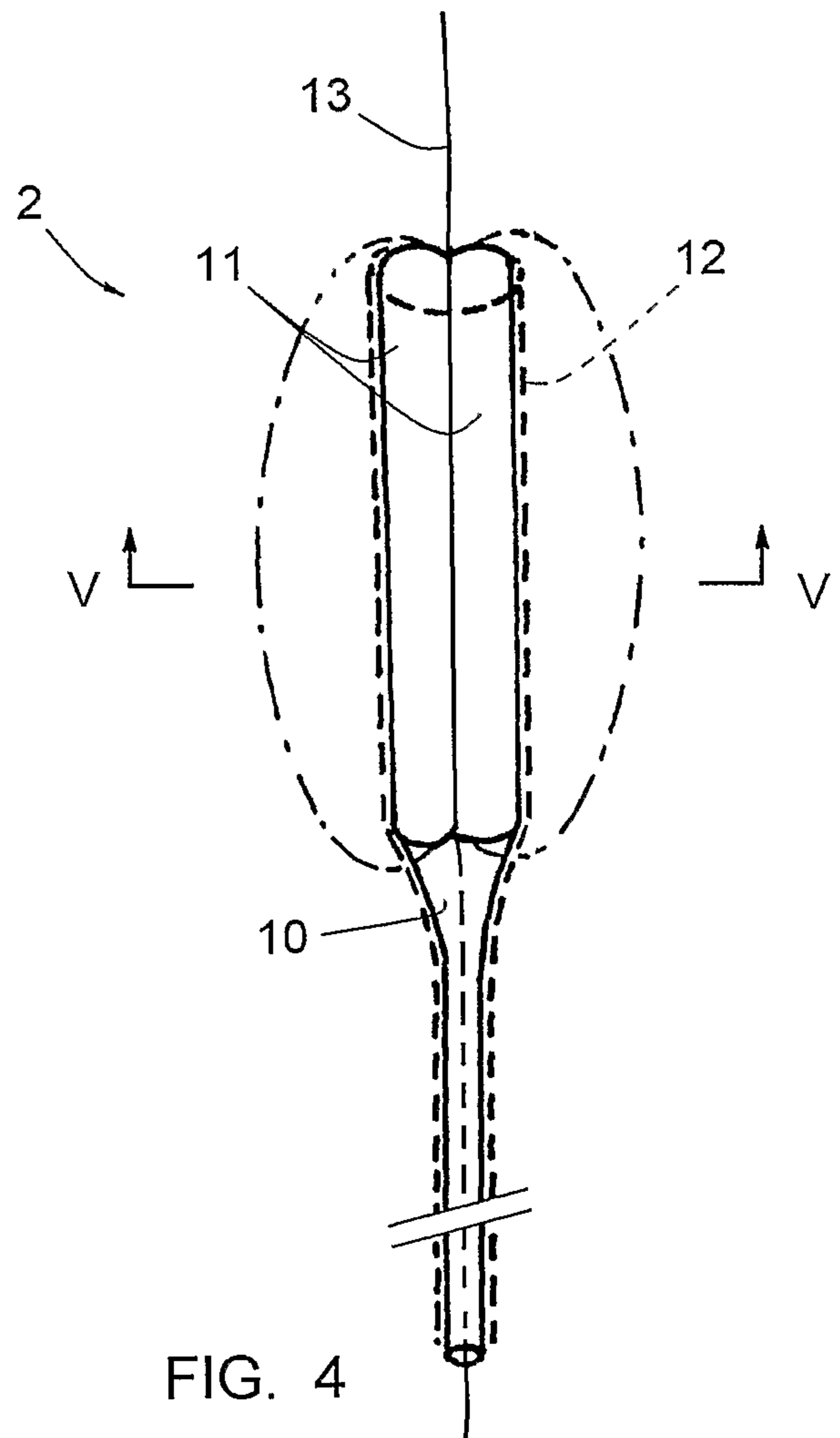


FIG. 4

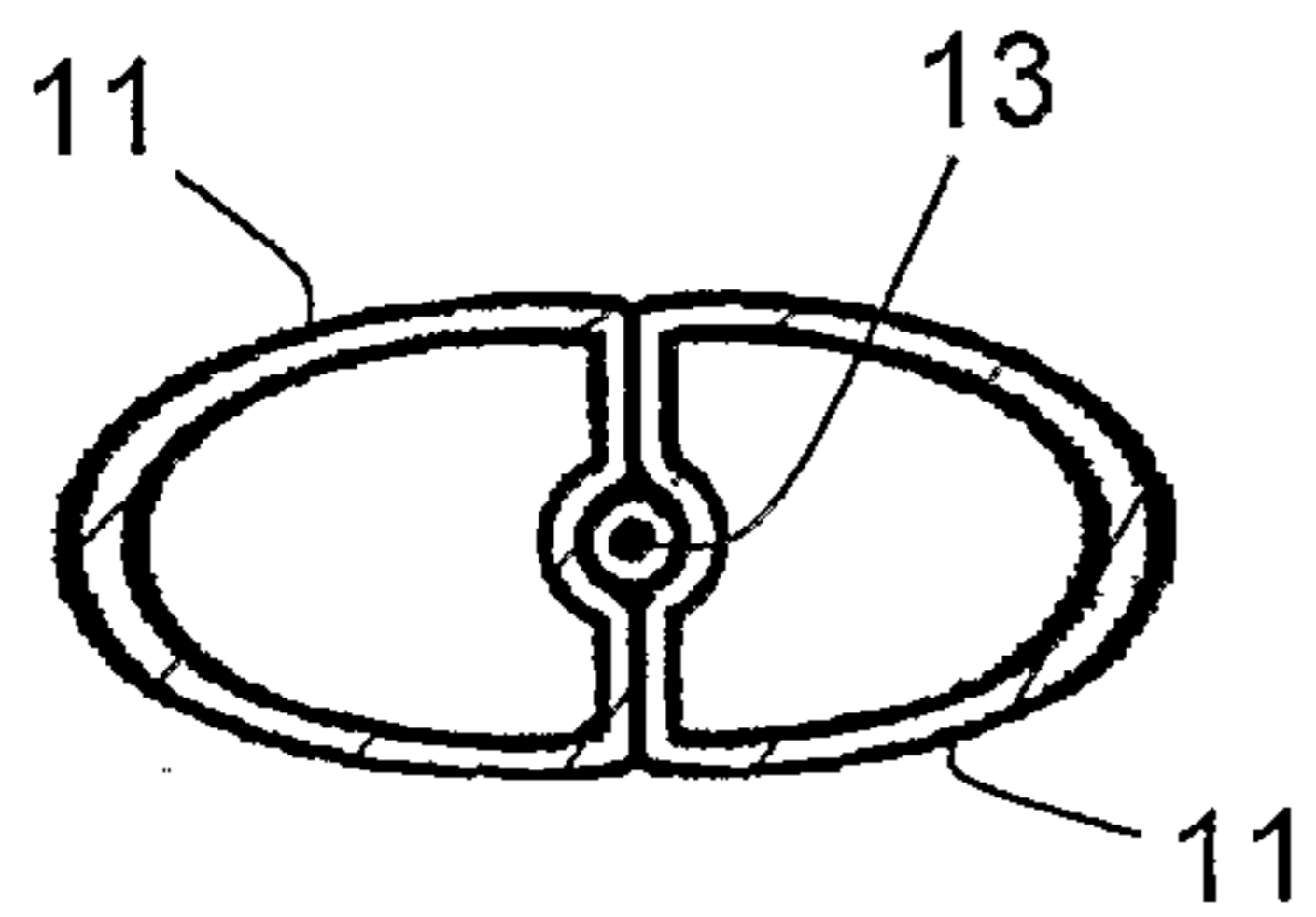


FIG. 5

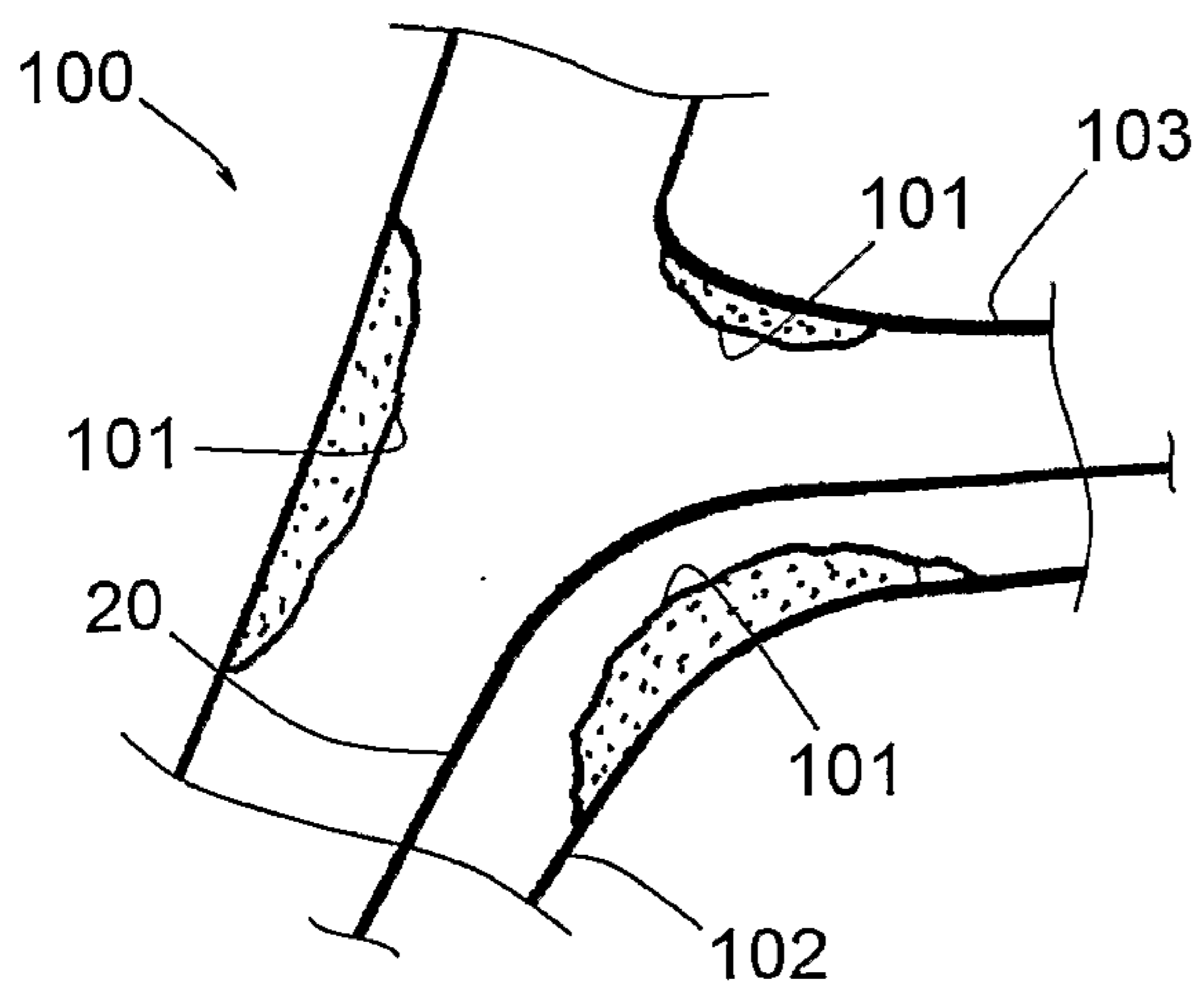


FIG. 6

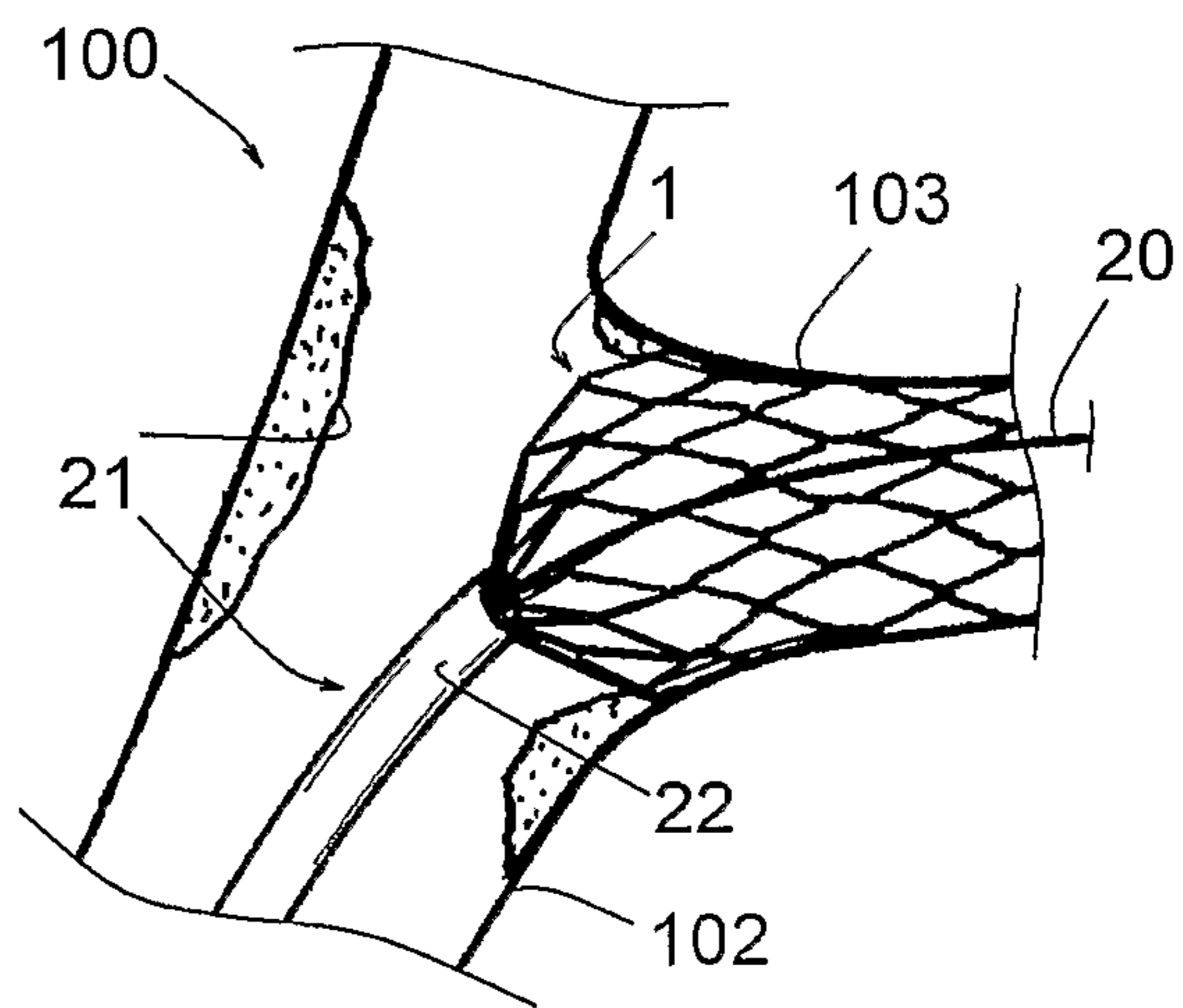


FIG. 7

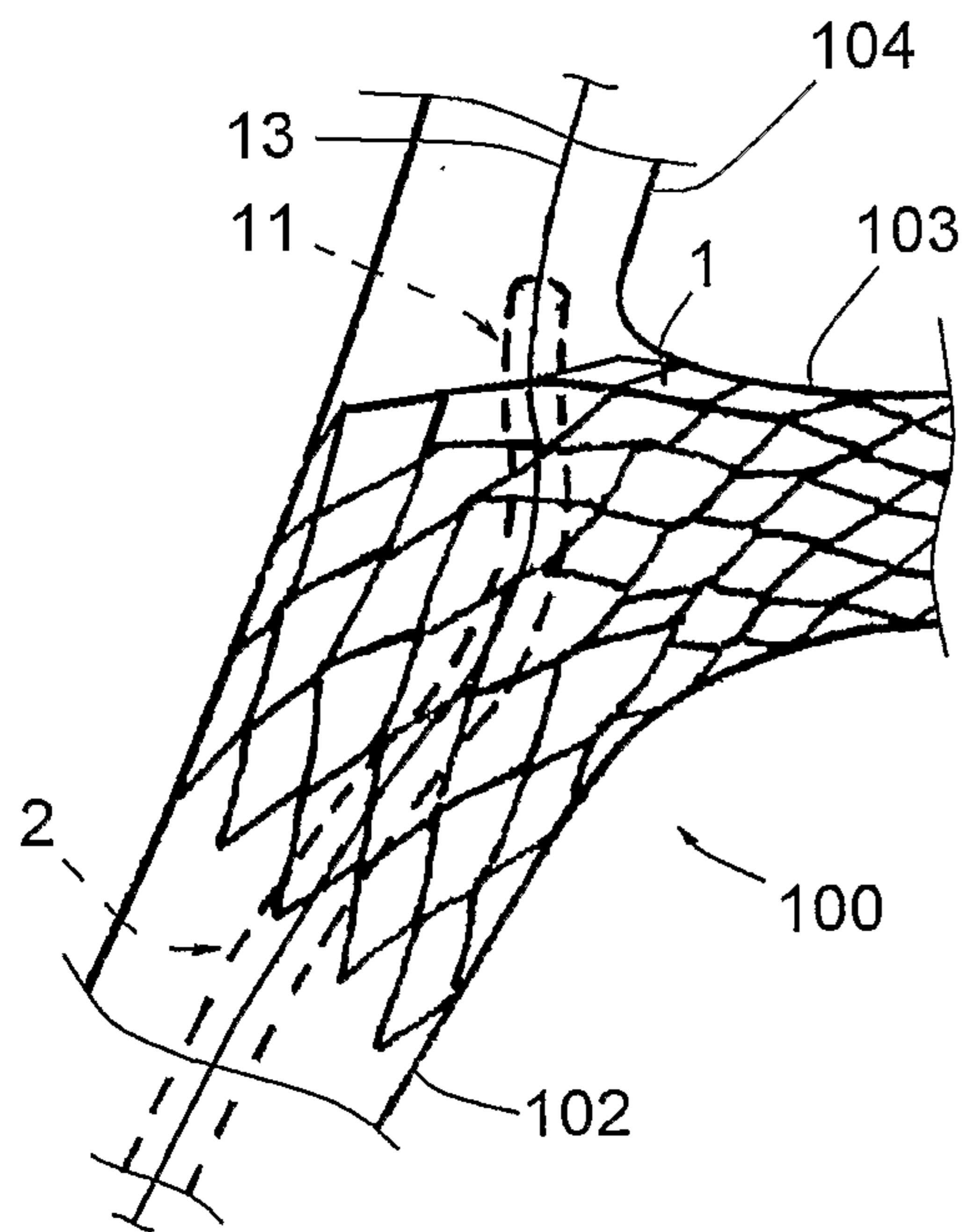


FIG. 8

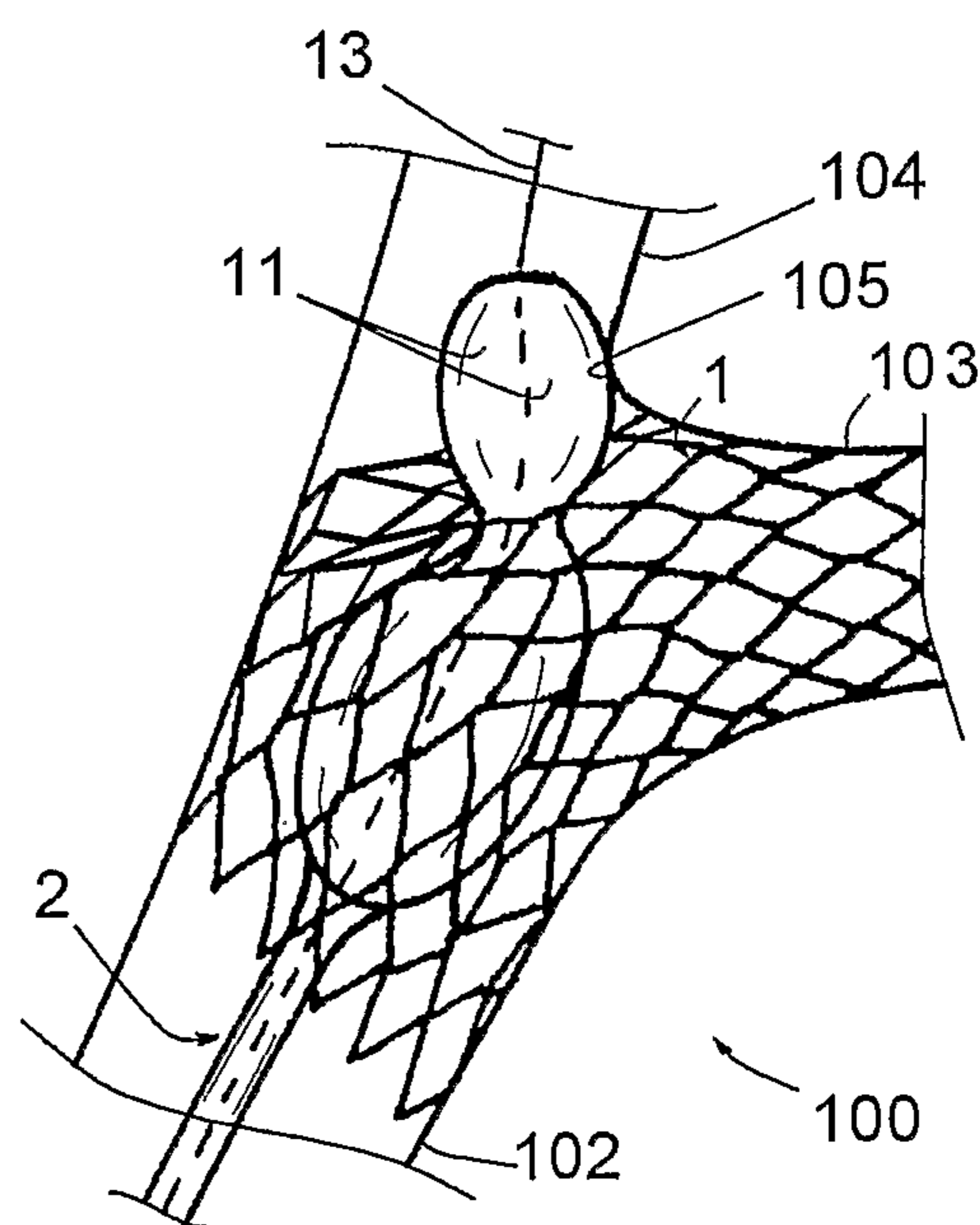


FIG. 9

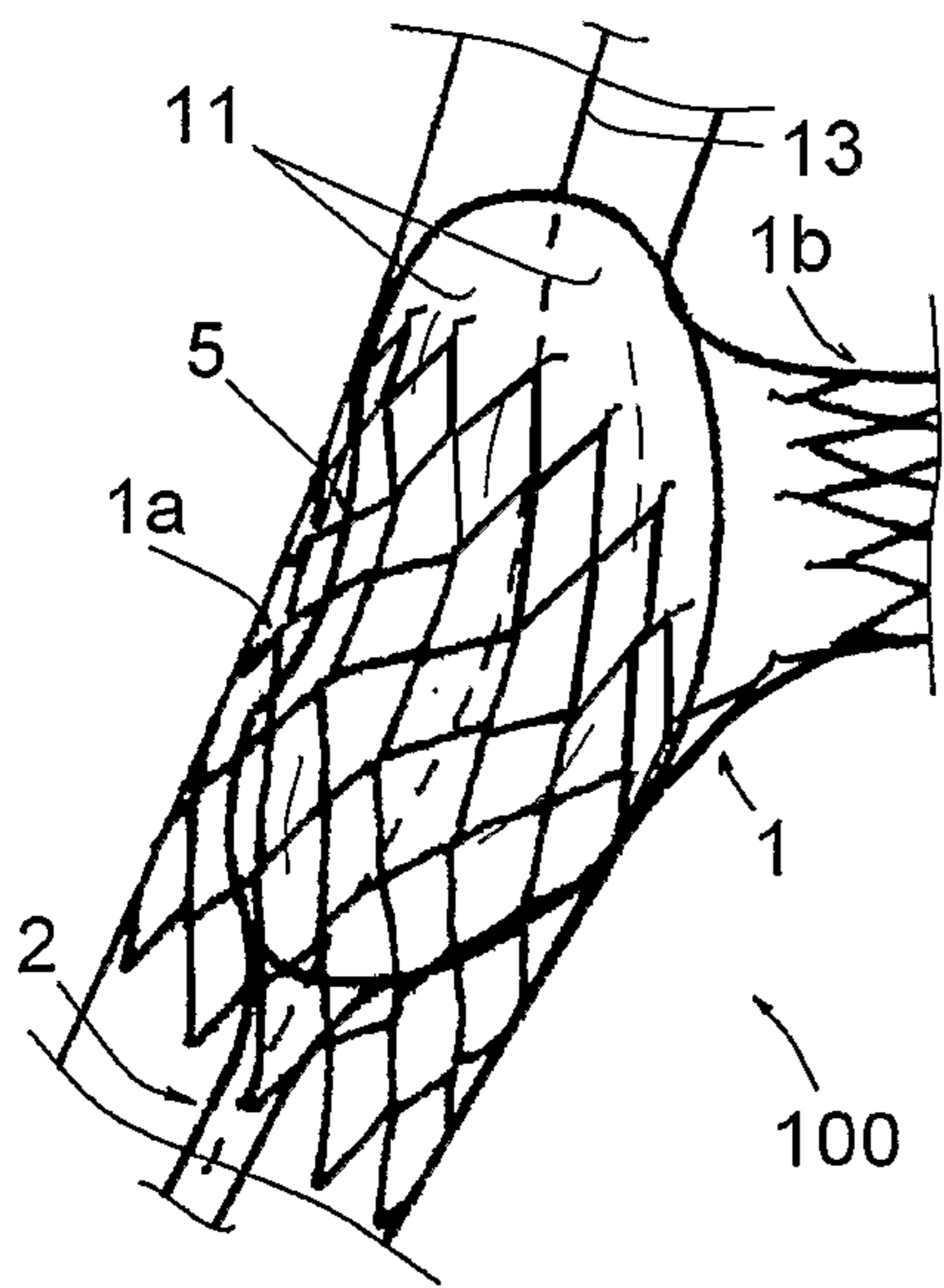


FIG. 10

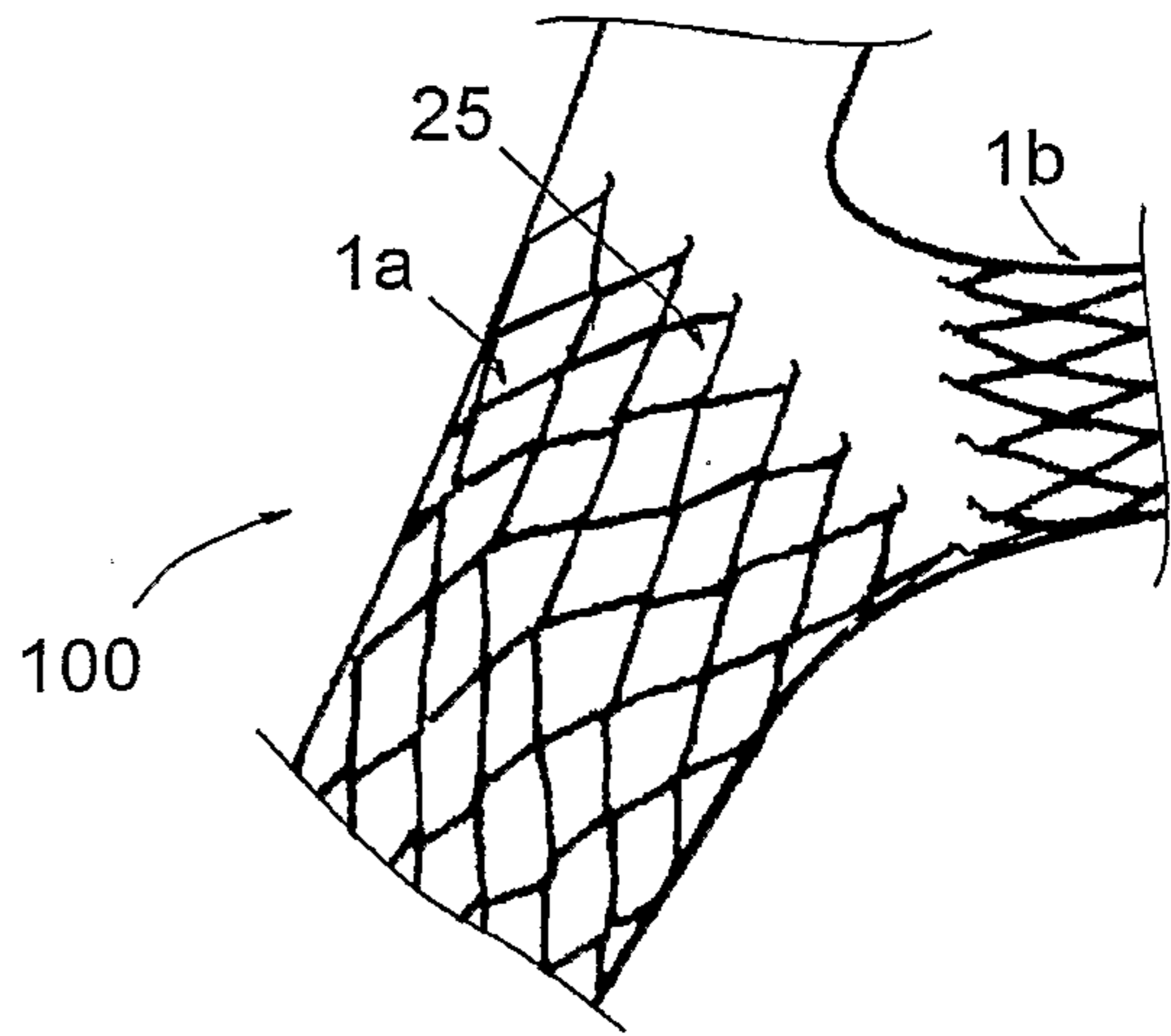


FIG. 11

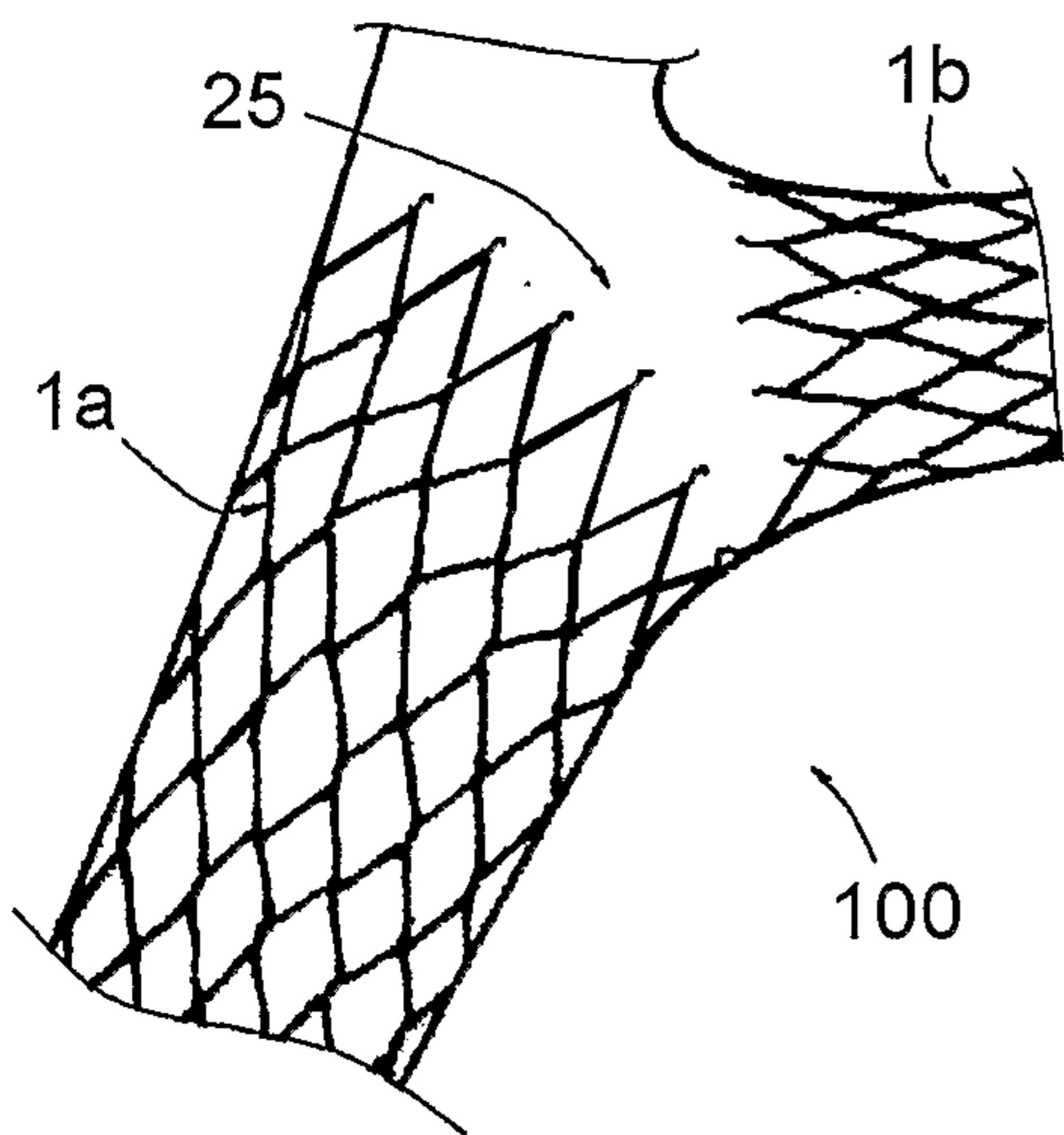


FIG. 12

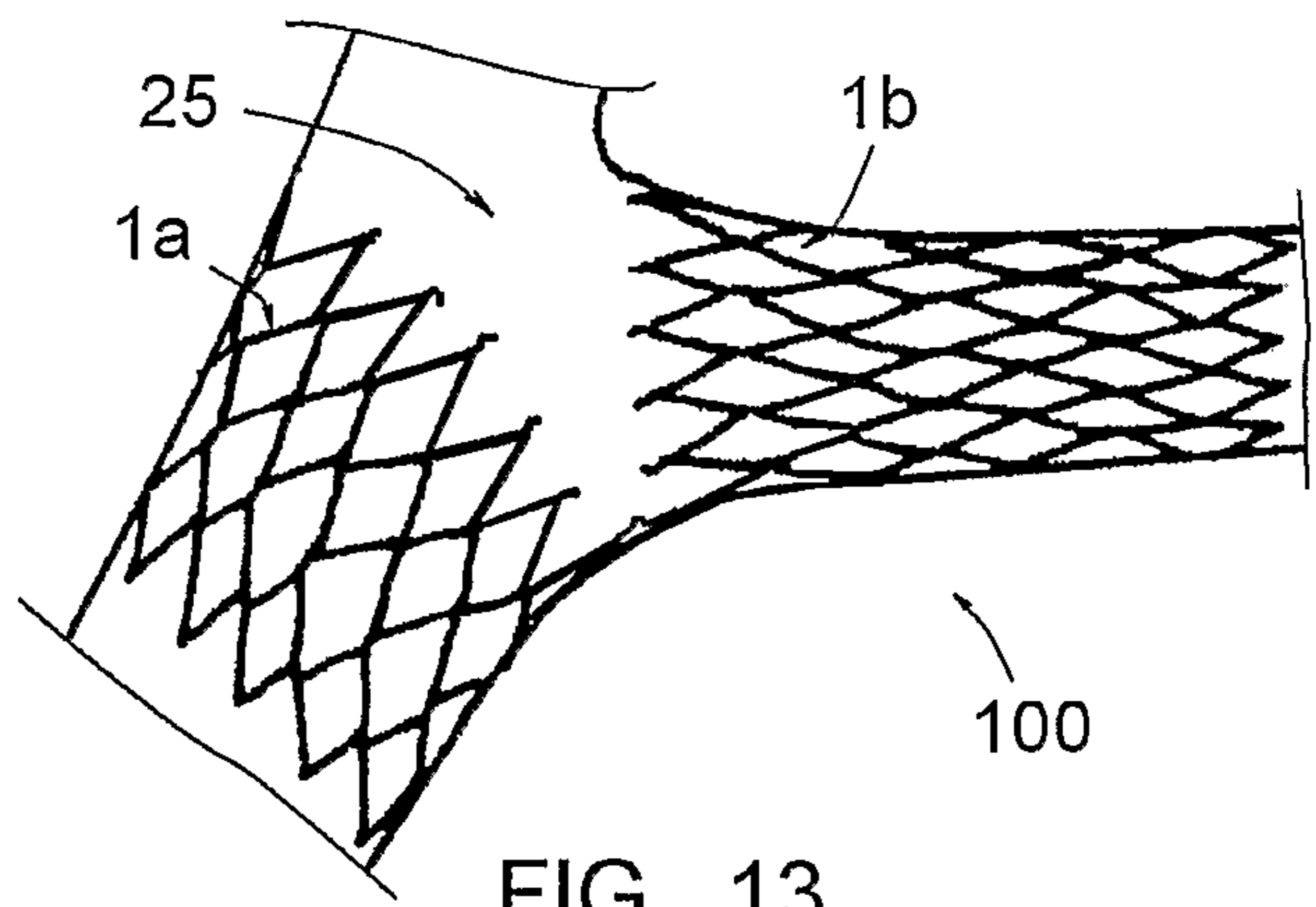


FIG. 13

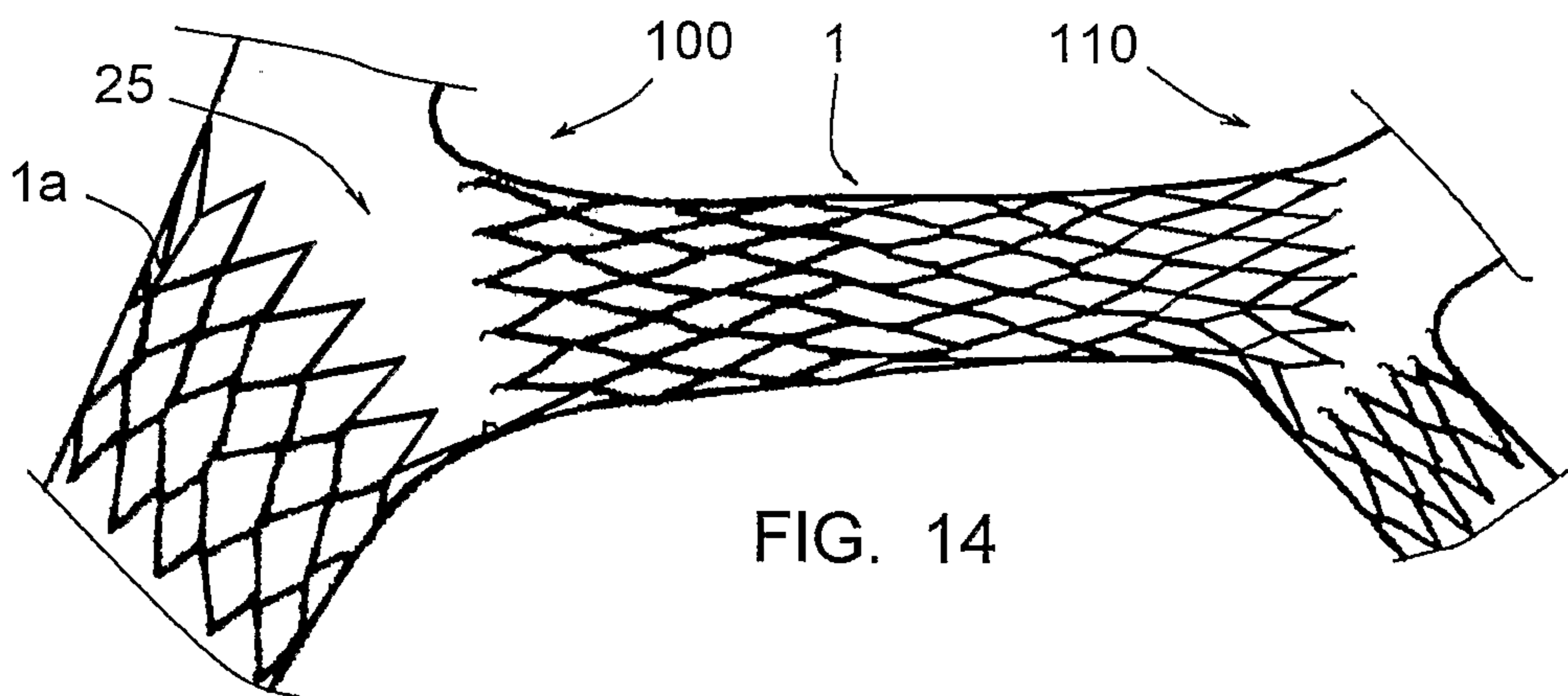


FIG. 14

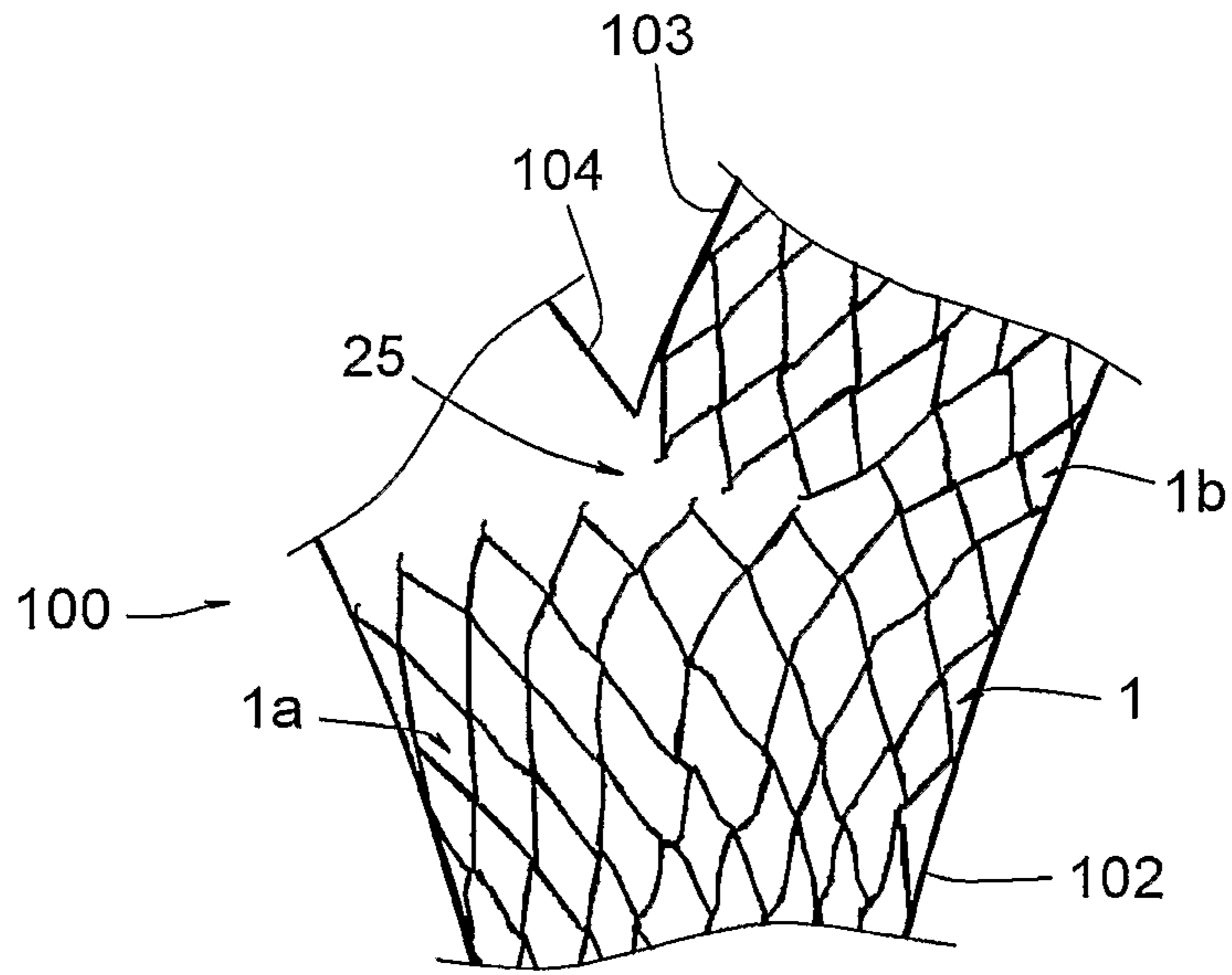


FIG. 15

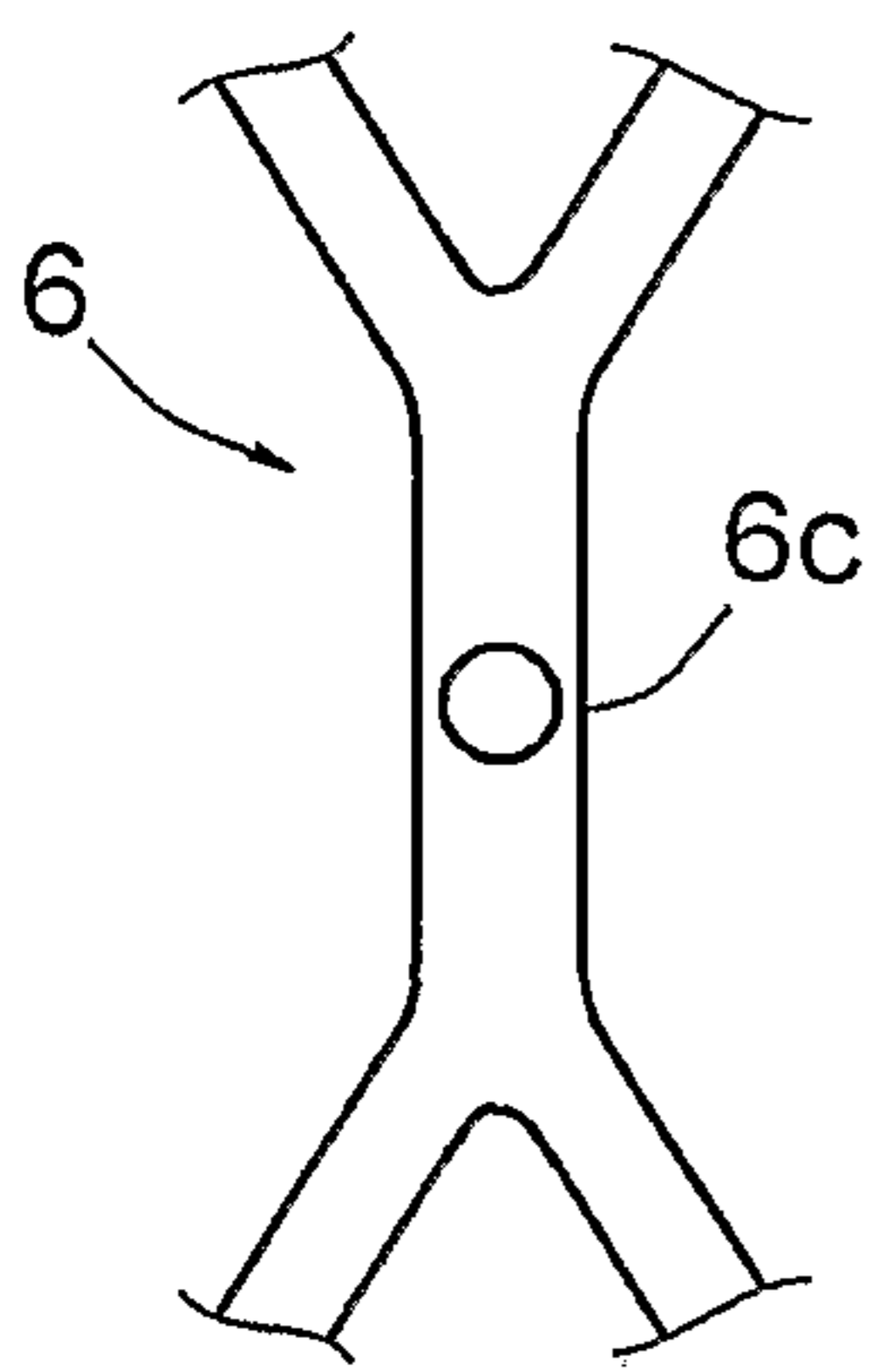


FIG. 16

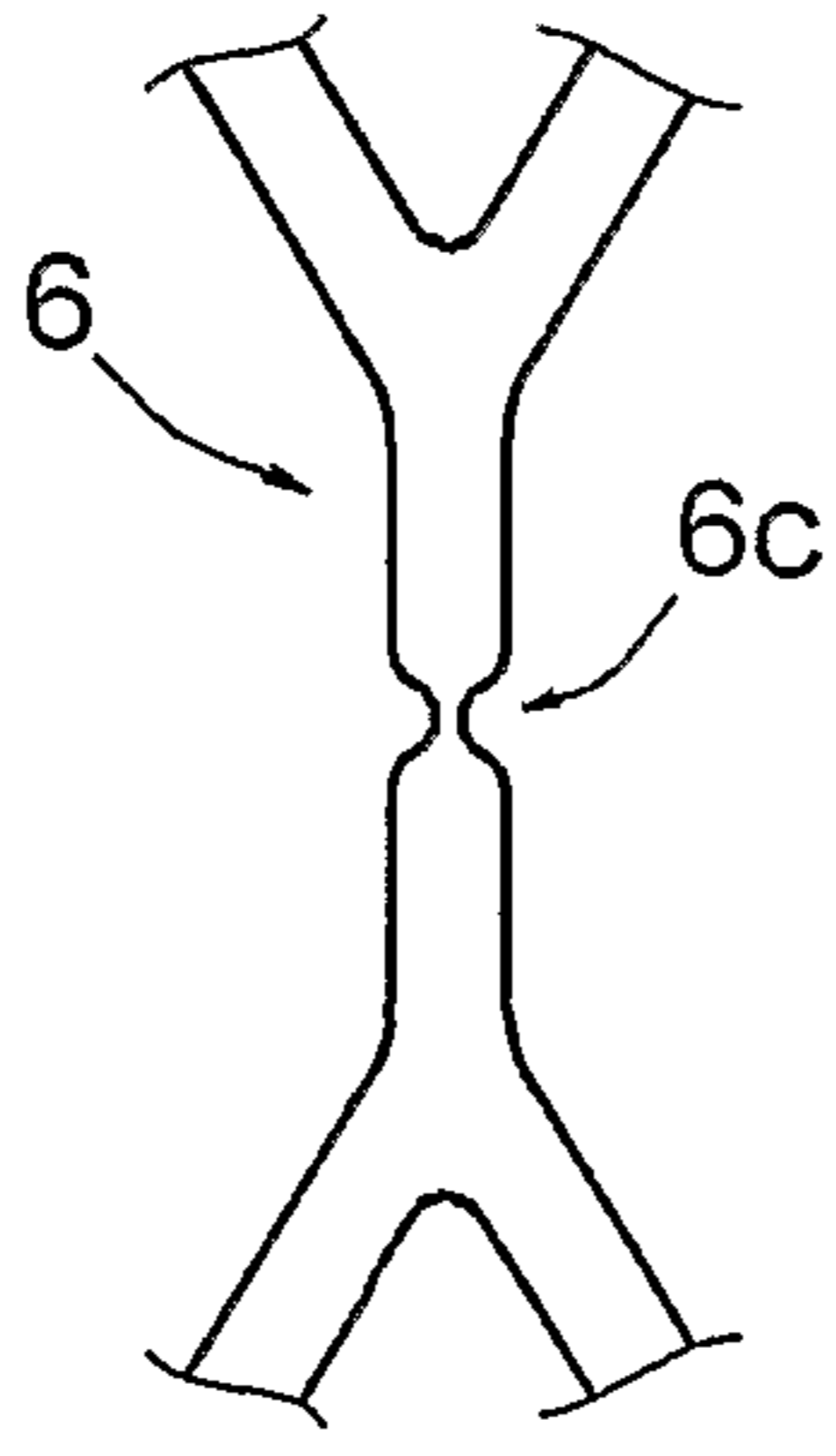


FIG. 17

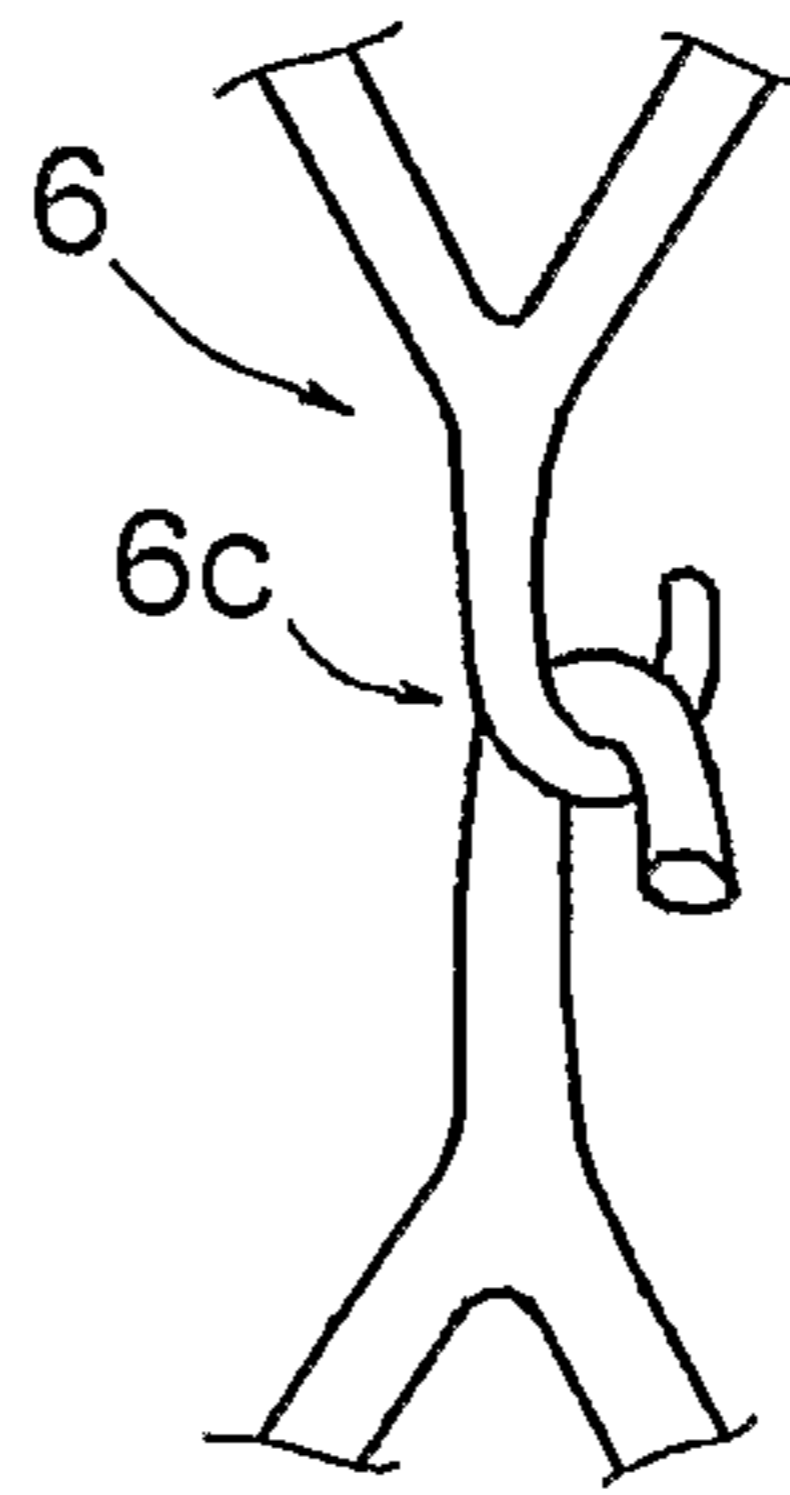


FIG. 18

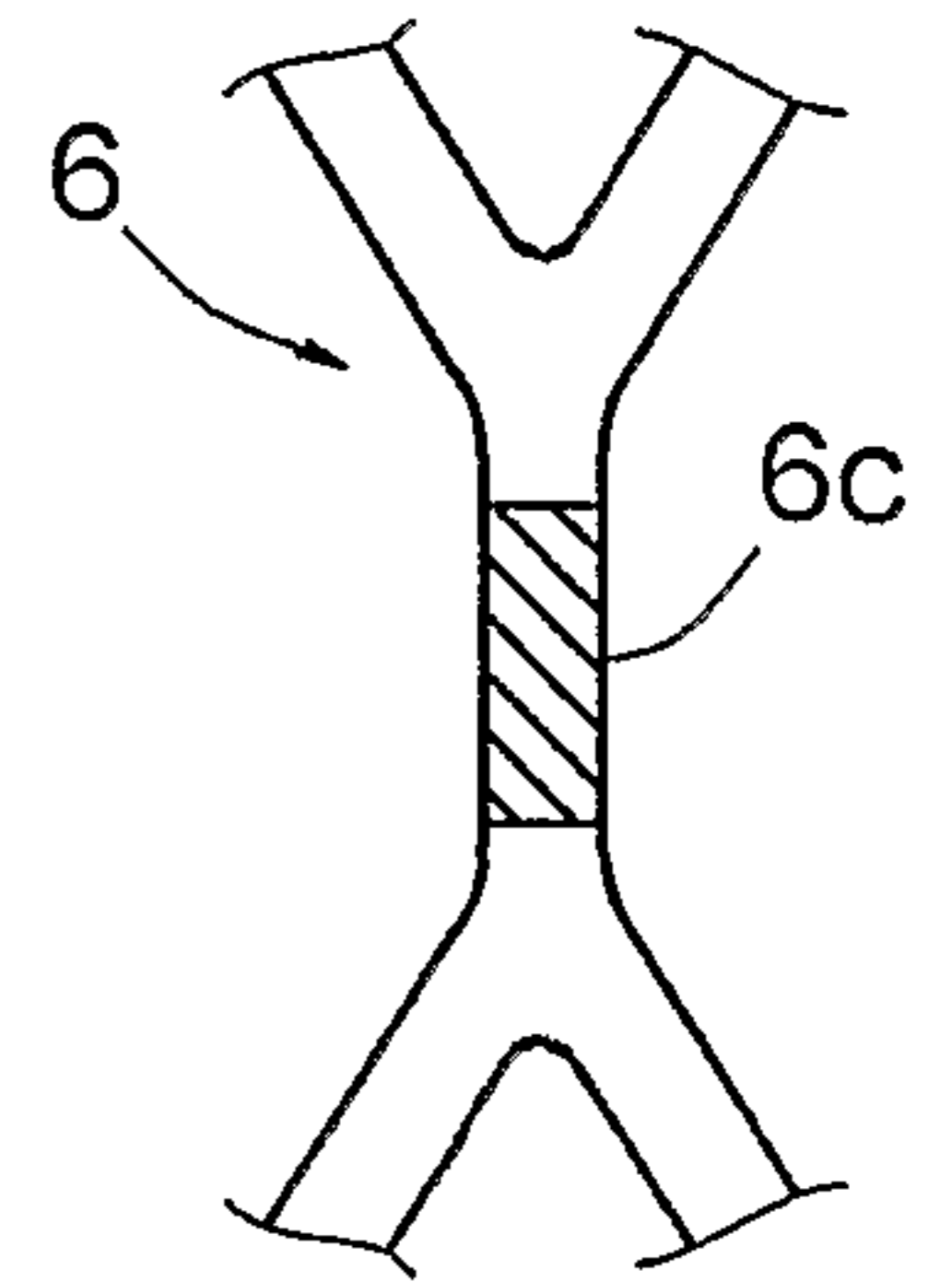


FIG. 19

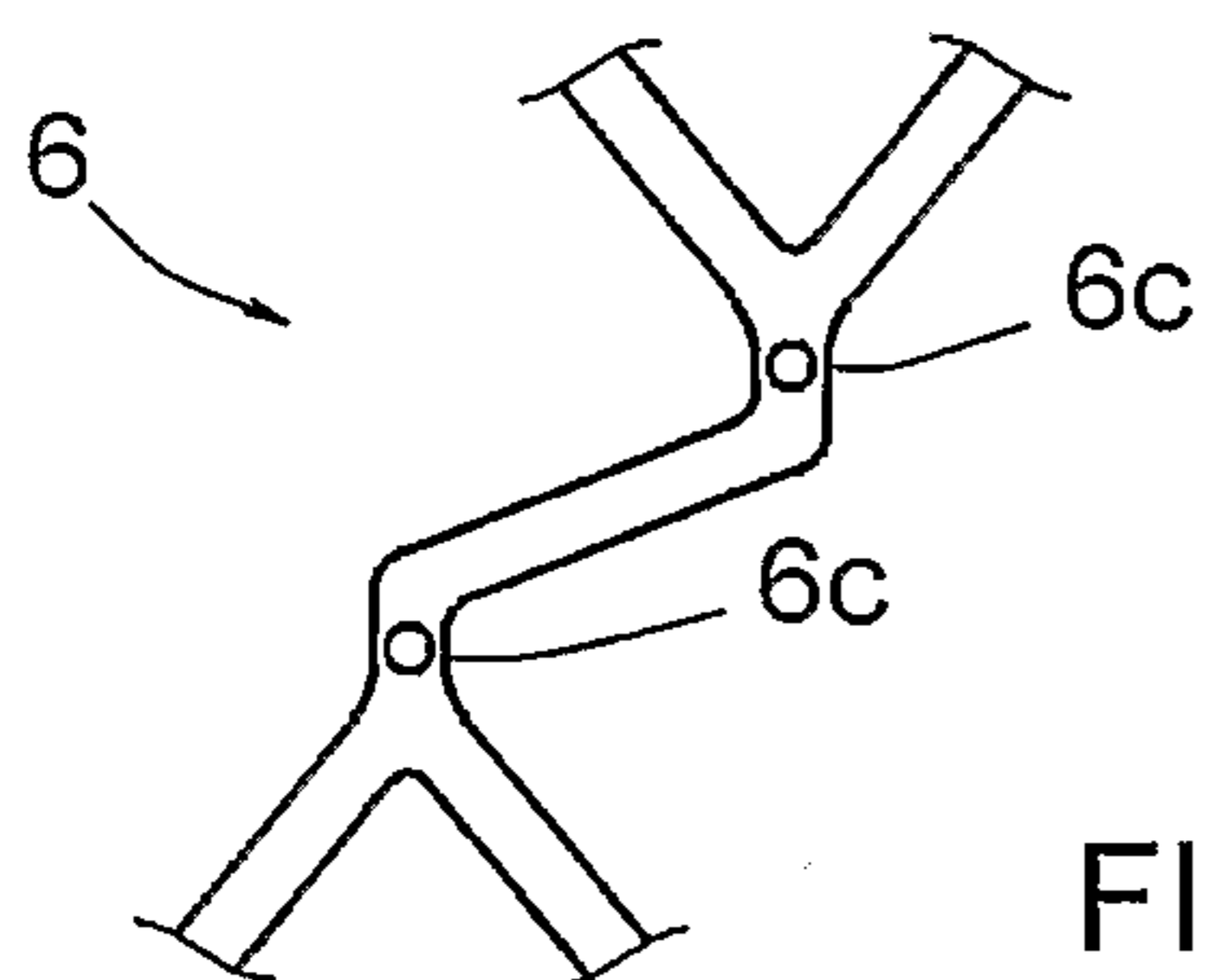
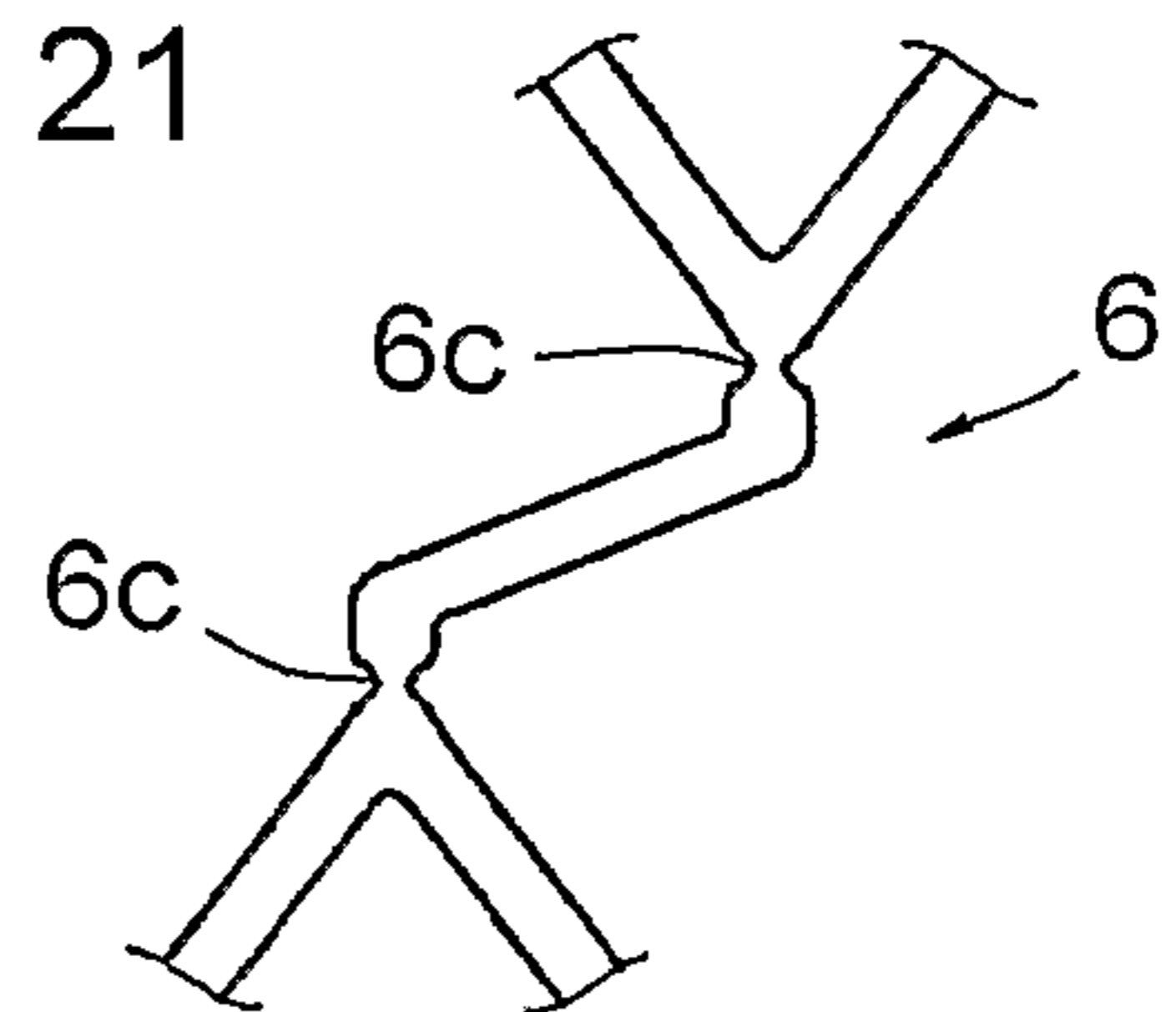


FIG. 20

FIG. 21



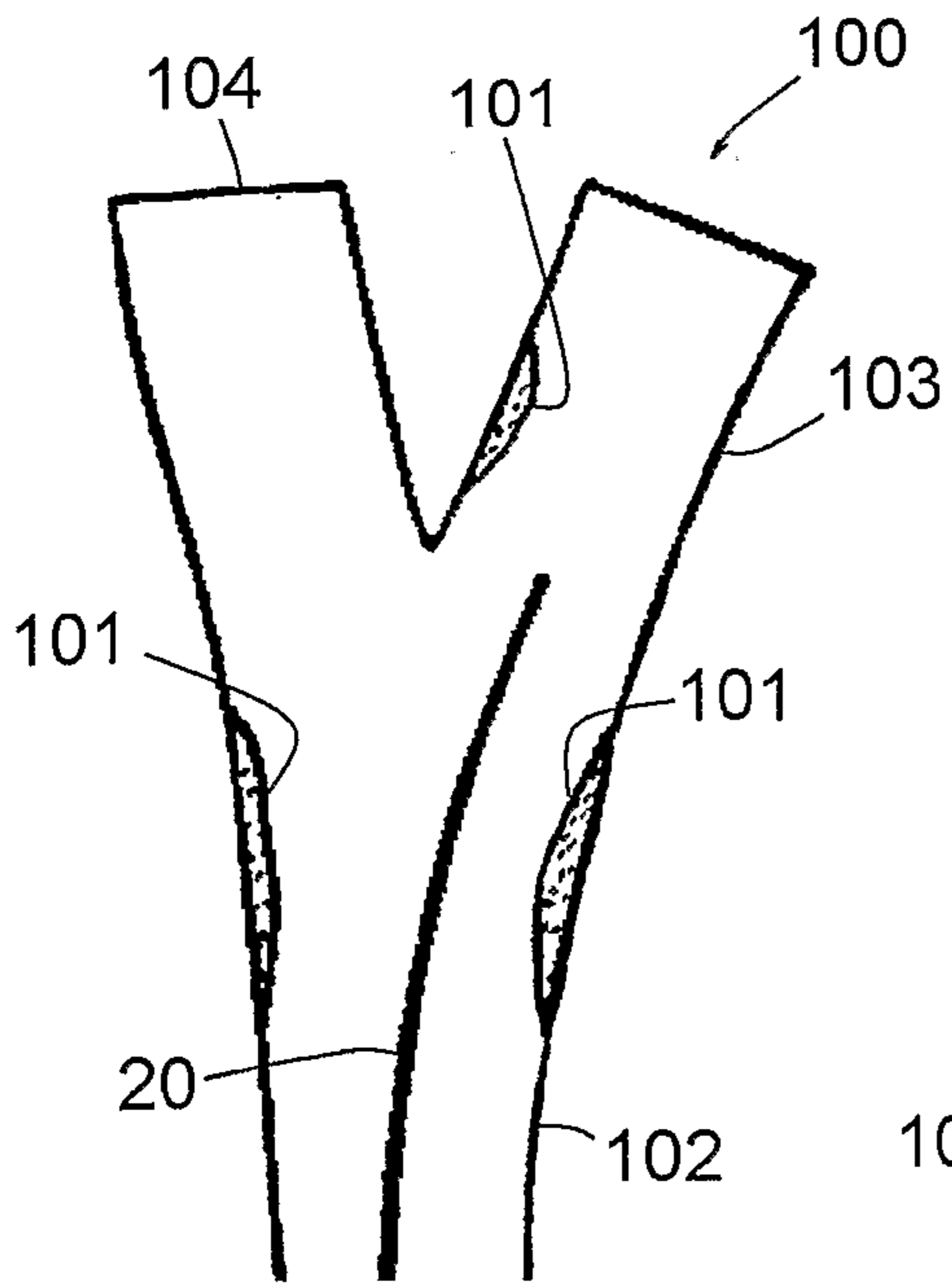


FIG. 22

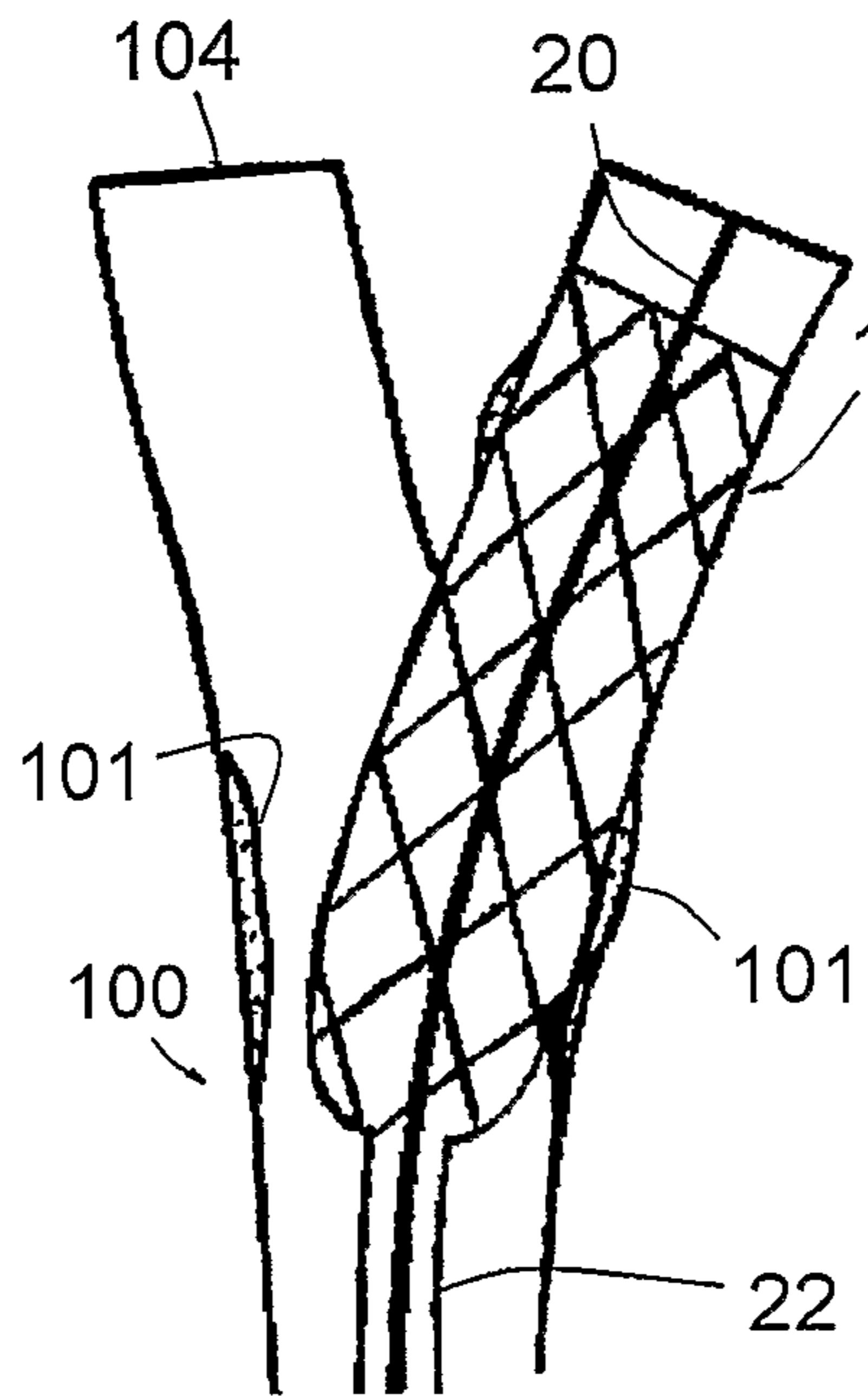


FIG. 23

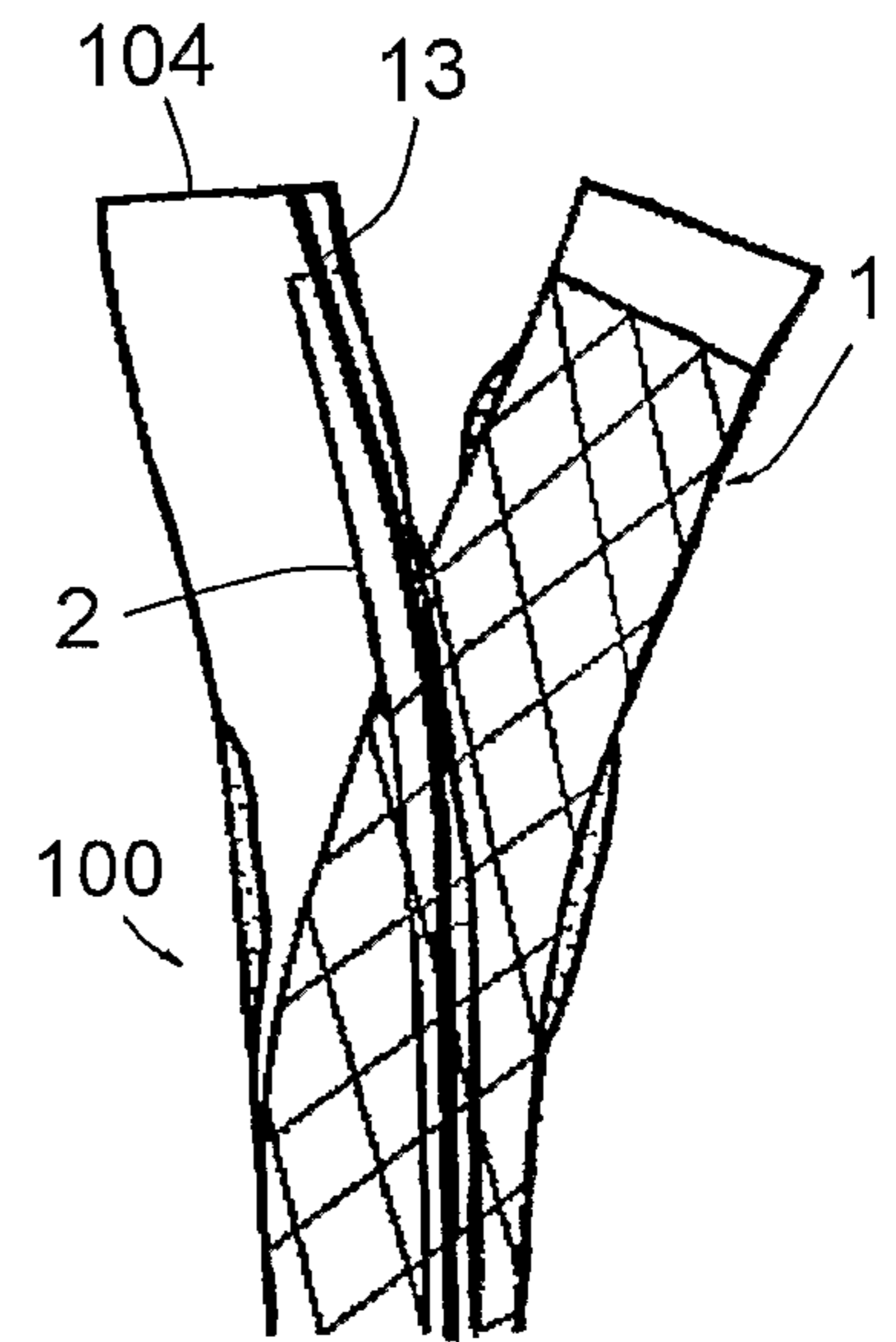


FIG. 24

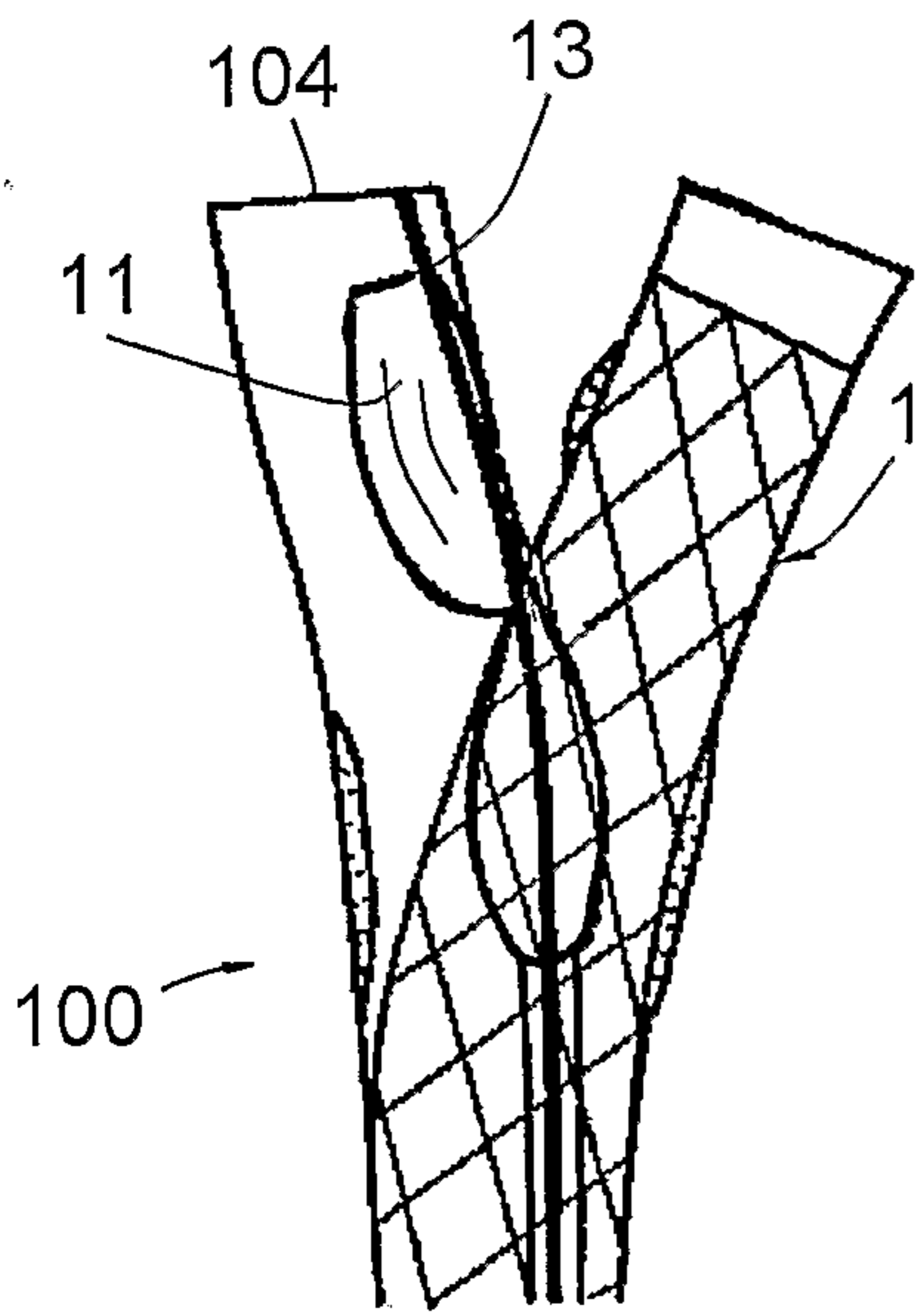


FIG. 25

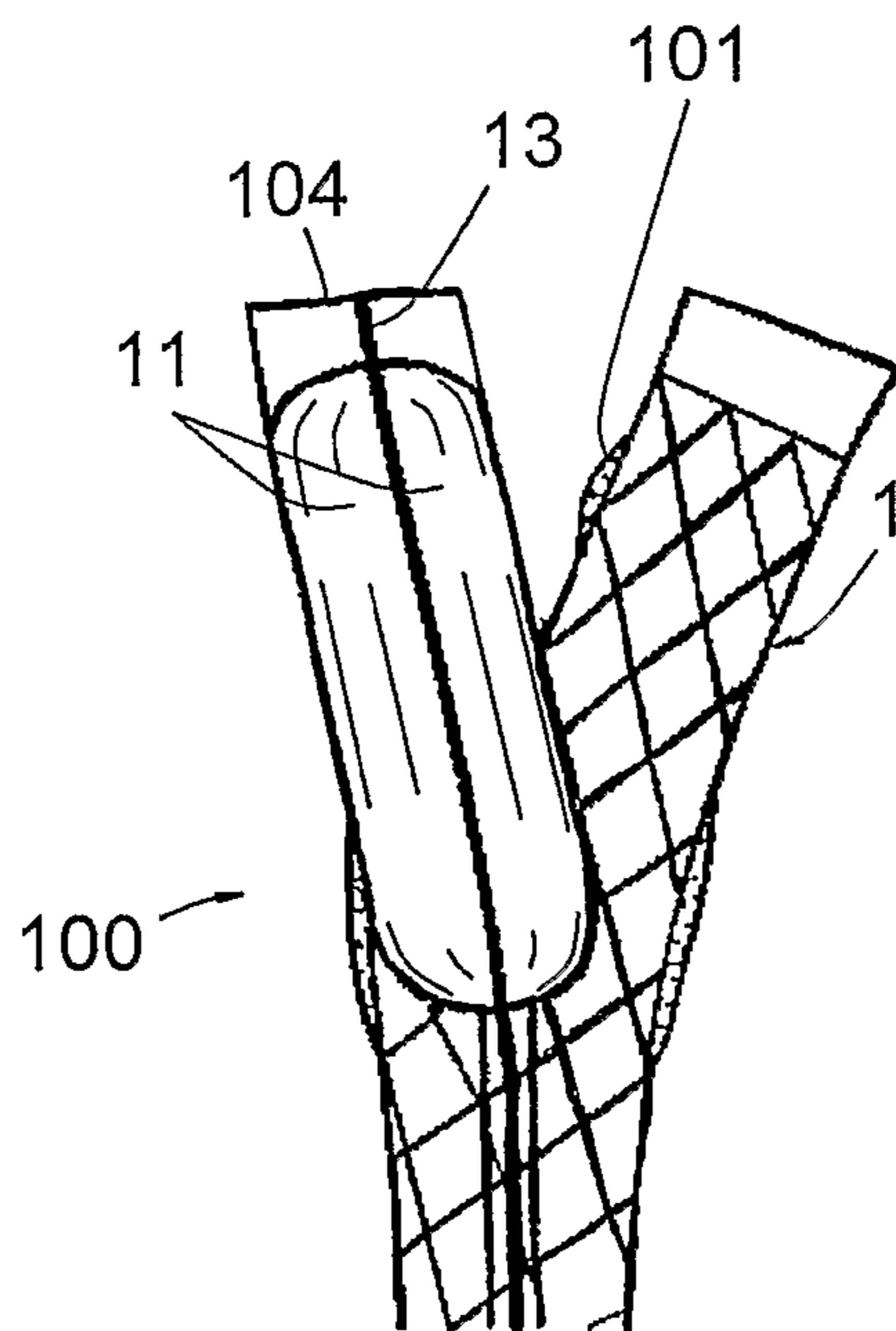


FIG. 26

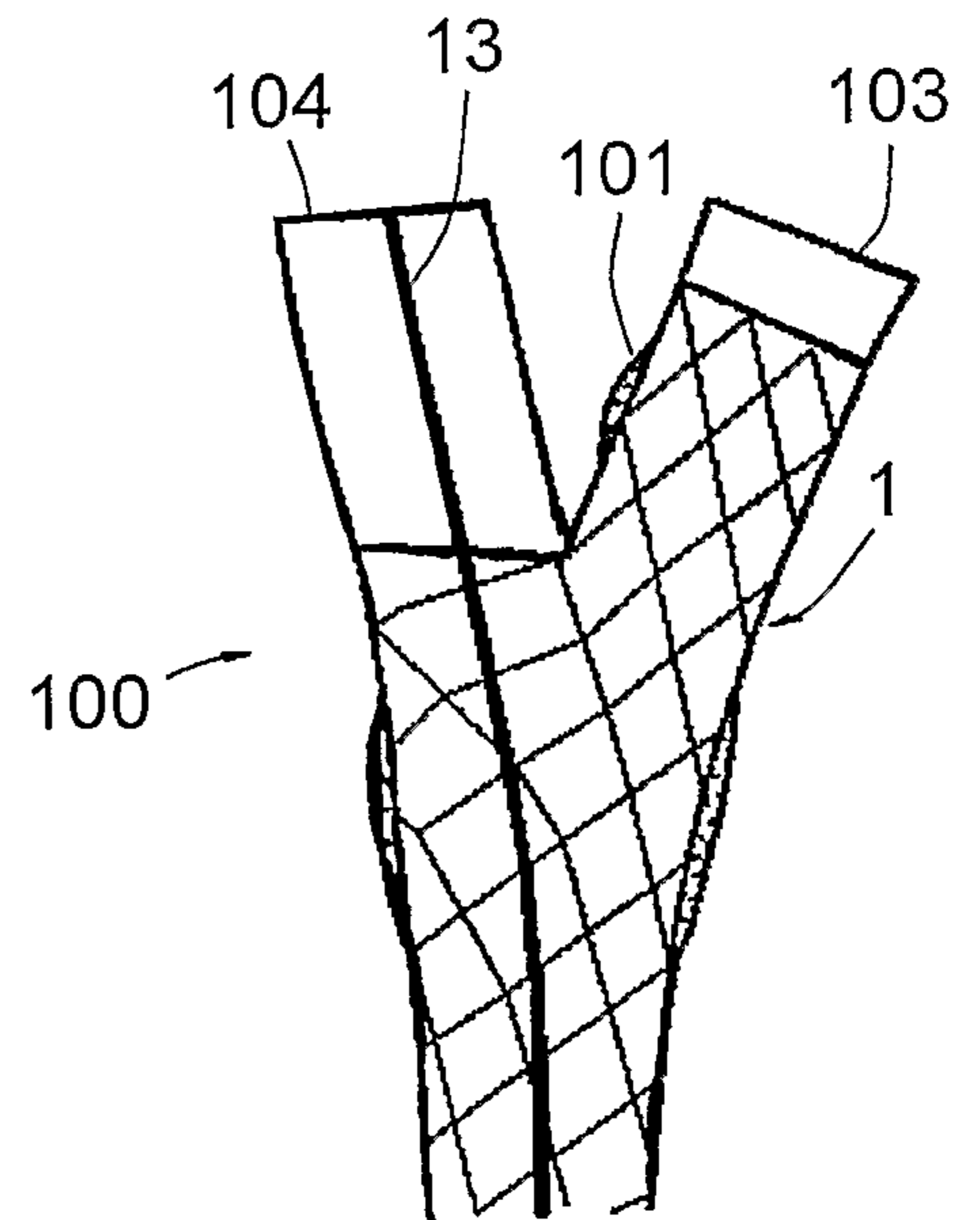


FIG. 27

