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(54) **Title:** IMPLANT FOR TREATMENT OF A HEART VALVE, IN PARTICULAR A MITRAL VALVE, MATERIAL INCLUDING SUCH AN IMPLANT, AND MATERIAL FOR INSERTION THEREOF

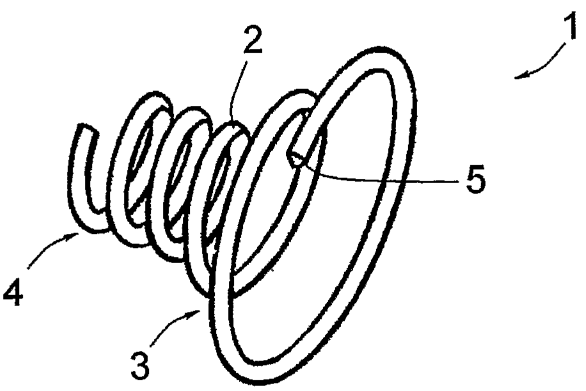

FIG. 1

(57) Abstract: This implant (1) is formed by a helically wound wire (2). According to the invention, it has dimensions such that it is able to be screwed into the wall of the annulus (103) and/or into the cardiac wall (101) adjoining this annulus (103) such that a portion of said annulus (103) and/or of said wall (101) is located in the perimeter of the implant (1); and it comprises at least one first coil able, during said screwing of the implant (1), to insert itself into said wall while having a first dimension and at least one second coil having a second dimension, or adopting this second dimension after implantation, said second dimension being smaller than the first dimension such that the implant (1), once inserted, enables contraction of said wall portion located in the perimeter of this implant (1).

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IMPLANT FOR TREATMENT OF A HEART VALVE, IN PARTICULAR A MITRAL VALVE, MATERIAL INCLUDING SUCH AN IMPLANT, AND MATERIAL FOR INSERTION THEREOF

The present invention concerns an implant for treatment of a heart valve, in particular a mitral valve of a heart, a material including such an implant and a material for insertion thereof. The treatment in question may consist of performing an annuloplasty, i.e. reducing a distension of the annulus, or strengthening the annulus of a normal valve. The invention also concerns a percutaneous intervention method for performing such a treatment.

The annulus of a heart valve can, over time, undergo a distension leading to poor coaptation of the leaflets, resulting in a loss of sealing of the valve.

To treat this affection, it is well known to perform an annuloplasty, i.e. re-calibration of the annulus using an implant inserted on the valvular annulus.

This annuloplasty implant can be a prosthetic annulus fixed on the native valvular annulus. This technique does, however, have the drawback of involving an open-heart operation.

The annuloplasty implant can also be a deformable elongated member, able to be introduced using a catheter through a minimally-invasive vascular approach, then able to be delivered via the catheter and fixed near the valvular annulus before being circumferentially retracted.

The existing annuloplasty implants of this type, and the corresponding implantation techniques, like the systems using the coronary sinuses, are not, however, fully satisfactory.

One existing implant, described by document N° WO 2006/091163, is formed by a helically wound wire, forming a split annulus having dimensions close to those of the valvular annulus. This implant is designed to be engaged on the base of the leaflets and to grip this base.

Moreover, it may be necessary to implant a prosthetic heart valve, in particular percutaneously using a catheter. Currently, this type of implantation is difficult on the mitral valve of a heart, percutaneously, essentially due to the fact that the annulus of a mitral valve is elastic and risks becoming distended upon percutaneous implantation of a prosthetic valve.

The present invention essentially aims to resolve the drawbacks and gaps of the prior art.

This implant is, in a known manner, made up of a helically-wound wire.

To this end, the implant according to the invention

- has dimensions such that it is able to be screwed into the wall of the annulus and/or into the cardiac wall adjoining this annulus such that one portion of this annulus and/or of this wall is located in the perimeter of the implant; and

- comprises at least one coil able, during said screwing of the implant, to be inserted in said wall while having a first dimension and at least one second coil having a second dimension, or adopting this second dimension after implantation, said second dimension being smaller than the first dimension such that the implant, once inserted, enables a contraction of said wall portion located in the perimeter of this implant.

The implant according to the invention thus has much smaller dimensions than those of the annulus of the valve to be treated, such that it can be placed locally in the wall of this annulus and/or in the cardiac wall adjoining this annulus. By "much smaller dimensions", one must understand that the implant has, in the plane perpendicular to its screwing axis, a maximum dimension at most equal to 15 mm, and generally in the vicinity of 10 mm, or smaller than 10 mm. This implant can have circular coils; said first coil(s) then have an external diameter of at most 15 mm. The implant can also have elliptical coils; said first coils then have a dimension of at most 15 mm along their largest axis.

"Screwing of the implant" designates a rotation of the implant along its axis, done so as to cause the helical coil formed by this implant to move in a direction. Below, the terms "front" and "rear" will designate the parts of the implant located on the front side or the rear side, respectively, in relation to the direction of screwing.

The implant is simply placed in the annulus and/or the cardiac wall, along a direction more or less perpendicular to the plane of the annulus, and makes it possible to achieve a local contraction of the tissue constituting this annulus and/or this wall. This contraction performs, in whole or in part, the annuloplasty. The radial contraction thus done also allows local strengthening of the annulus.

When said radial contraction only partially performs the aforementioned annuloplasty and/or strengthening, a plurality of implants according to the invention can be inserted closer and closer on the annulus and/or the wall, or on a portion of this annulus and/or this wall, to perform all of the desired annuloplasty and/or strengthening.

According to one possible formation of the coils, said first coil(s) are located, in the direction of screwing of the implant, in front of said second coil(s).

During screwing of the implant, said first coil(s) penetrate first into the annulus and/or the cardiac wall and form a path having corresponding dimensions, which will then be used by said second coil(s), of smaller dimensions, thereby bringing about the radial contraction of said portion of the annulus and/or wall.

The coils of the implant can be circular, as already mentioned, or have a non-circular shape, in particular oval or elliptical.

The implant performs an additional contraction of the annulus and/or of said adjoining wall according to its angular position in this annulus and/or this wall.

According to another possible formation of the coils, the wire making up the implant is in a shape memory material, defining, in a first state, coils having said first dimension and, in a second state, coils having said second dimension.

The passage of these coils from said first dimension to said second dimension, by shape memory, causes the contraction of said portion of the annulus located in the perimeter of these coils of the implant.

The possible formations of the coils mentioned above can be combined on a same implant. Thus, for example, an implant can comprise at least one coil having a larger diameter and at least one coil having a smaller diameter, and be in a shape memory material such that the diameter of the coils is reduced after implantation; an implant can be in a shape memory material such that it comprises circular coils at the time of its implantation, assuming a non-circular shape after implantation.

The front end of the wire constituted by the implant is preferably pointed or sharp, so as to facilitate its penetration into the tissue of the annulus and/or said cardiac wall.

The wire constituting the implant can have a same structure along its entire length, or comprise portions in a first material and portions in a second material different from the first material. For example, the implant can comprise portions in non-shape memory wire and portions in shape memory wire; the implant can comprise portions of wire in a non-resorptive material and portions of wire in a resorptive material.

The wire constituting the implant can for example be in stainless steel or in a shape memory material such as an alloy of nickel and titanium known by the name "nitinol", or in a material using superelasticity, or in a resorptive material.

The wire constituting the implant can also comprise portions of different structures, for example solid, resistant portions and portions having a thinner cross-section able to be broken in the event of radial forces directed toward the exterior. In this second case, the implant can, for example, be used on children, and break under the effort of said stresses resulting from the growth of the patient.

The implant can comprise radiopaque markers enabling its visualization through the patient's body, in particular markers enabling visualization of the angular orientation of the implant when the latter comprises non-circular coils.

The implant can also comprise means ensuring its anchoring in the tissue with regard to screwing or unscrewing; for example, a rear portion of the wire can, by shape memory, bore itself in such that the wire can no longer slide in relation to the tissue in which the implant is placed; the implant can also comprise protruding portions, for example in the form of claws, deploying via shape memory.

The material including the implant according to the invention comprises means making it possible to connect at least two adjacent implants placed in an annulus, so as to achieve a contraction of the wall of the annulus located between the implants, in addition to the contraction achieved by the implants themselves. It can in particular involve wires in a material able to be twisted, in particular in a metallic material, connected to the proximal parts of the implants, these wires being engaged in a same catheter then being twisted in order to bring the two implants closer together.

It can also involve wires or strips in metal or in a material using superelasticity, or a shape memory material connecting two implants, able to be shortened after implantation.

The material for insertion of an implant according to the invention includes at least one catheter able to deliver the implant, means for longitudinal movement of the implant in relation to this catheter and means for driving the implant in rotation along the axis of the implant.

The material according to the invention thus enables precise insertion of the implant, using a minimally-invasive approach.

The longitudinal movement means may comprise a push-rod slidingly engaged in the catheter.

The rotational driving means may comprise a wire separably connected to the rear end of the implant.

The separability of the wire connected to the rear end of the implant can in particular be achieved via a removable connection of this wire and this end, in particular using an assembly via reversible locking, being released via traction on the wire.

The percutaneous intervention method according to the invention comprises the steps consisting of:

- using the implant and the material as mentioned above;
- bringing the distal opening of the catheter comprised by the material across from the area designed to receive the implant;
- causing the implant to move forward in relation to the catheter while driving this implant in rotation along its axis, in order to perform screwing of the implant into the annulus of the valve to be treated and/or the cardiac wall adjoining this annulus;
- if needed, repeat the preceding steps so as to insert as many implants as necessary to perform the desired annuloplasty and/or the strengthening of the annulus.

The step consisting of bringing the distal opening of the catheter across from the area designed to receive the implant may be done by approaching the valve via one or the other of the sides of this valve, in particular, involving the treatment of a mitral valve, either via a ventricular approach or an auricular approach.

The invention will be well understood, and other characteristics and advantages thereof will appear, in reference to the appended diagrammatic drawing, illustrating, as non-limiting examples, several possible embodiments of the implant and the material it concerns.

Figure 1 is a perspective view of the implant according to a first embodiment;

figure 2 is a perspective view of the implant according to a second embodiment;

figure 3 is a flat diagrammatic view of a coil of the implant;

figure 4 is a flat diagrammatic view of a coil of another implant;

figure 5 is a view of a heart in partial cross-section, during a first step of insertion of the implant according to the invention;

figures 6 to 9 are views of four successive steps for insertion of the implant;

figure 10 is a view of the implant along a direction perpendicular to figure 9;

figure 11 is an outline sketch of a mitral valve in which three implants have been inserted;

figure 12 is a side view of a push-rod comprised by the material according to the invention;

figure 13 is an end view of this push-rod;

figure 14 is a view of one variation of embodiment of the material according to the invention;

figure 15 is a view of another variation of embodiment of the material according to the invention;

figures 16 and 17 are still further views of another variation of embodiment of the material according to the invention;

figure 18 is a view of another embodiment of the implant according to the invention;

figures 19 to 22 are views of yet another embodiment of the implant according to the invention, during four successive steps of insertion;

figures 23 to 30 are views of yet another embodiment of the material according to the invention;

figure 31 is a partial perspective view of a heart annulus having a series of implants according to another embodiment, placed in its wall, and

figure 32 is an enlarged perspective view of two implants from this series of implants.

Figure 1 illustrates an implant 1 for treatment of a heart valve, in particular a mitral valve of a heart, this treatment being able to consist of performing an annuloplasty, i.e. reducing a distension of the annulus, or strengthening the annulus of a normal valve.

As illustrated, the implant 1 is formed by a helically wound wire 2 and comprises a conical portion 3 and a cylindrical portion 4. The conical portion 3 is made up of coils whereof the diameter decreases in the direction of the cylindrical portion 4, which is formed by coils having a constant diameter.

The end 5 of the wire 2 at the level of the coil having the largest diameter of the conical portion 3 is pointed, so as to be able to pierce the tissue constituting the annulus of a mitral valve and/or the wall of the ventricle adjoining this annulus.

Figure 2 illustrates an implant 1 having a similar structure but having a purely conical shape, i.e. comprising coils whereof the diameter decreases from one end of the implant to the other.

Figure 3 shows that the implant 1 can have circular coils and figure 4 shows that the implant 1 can comprise coils having an elliptical shape.

Figures 5 to 10 show one possible procedure for inserting one or the other of the aforementioned implants 1.

During a first step, a catheter containing a hollow piercing needle is introduced via the aorta 100, up to the left ventricle 101 then is engaged between the pillars 102 until the distal end of the catheter arrives against the ventricular wall in the immediate vicinity of the annulus 103 of the mitral valve. To follow this journey, the catheter can present appropriate successive curves or can be of the "deflectable" type, i.e. able to be oriented using sliding wires which it comprises in its wall.

Once this catheter is in place, the needle is deployed to pierce the ventricular wall, and a guide wire 10 is slid through this needle to the inside of the left auricular appendix 104.

The catheter is then removed while still keeping the wire 10 in place, and another catheter 11, containing the implant 1, is slid on the wire 10 until its distal opening is in the immediate vicinity of the mitral annulus 103, as shown by figure 5.

It appears in figure 6 that this catheter 11 comprises two diametrically opposed ducts 12 wherein are engaged and can slide two wires 13 whereof the distal ends are bent. These distal ends are elastically deformable such that they can adopt a substantially rectilinear shape enabling the wires 13 to slide in the ducts 12, and resume their neutral curved shape when they are outside these ducts 12.

Once the distal end of the catheter 11 is in contact with the ventricular wall, these distal ends are deployed outside the ducts 12 and penetrate inside this ventricular wall, ensuring that the catheter 11 is kept in position.

The implant 1 is contained in its stressed state in the catheter 11, and its rear end is removably connected, by reversible locking, to a wire 14. This wire 14 is engaged through a radially offset opening 15 comprised by the distal end wall of a hollow push-rod 16 engaged in the catheter 11, this push-rod 16 being able to pivot in the lumen of the catheter 11.

Figure 12 and 13 more particularly show the push-rod 16 and its opening 15.

The push-rod 16 is used to screw the implant 1 into the ventricular wall, i.e. to move this implant 1 longitudinally in relation to the catheter 11 so as to remove the latter while driving it in rotation around its axis. During this screwing, the first coil having the largest diameter first penetrates the ventricular wall and forms a path corresponding to its diameter, which will then be used by the following coil of smaller diameter, and so on (cf. figures 7 and 8). Each coil of smaller diameter then produces a radial contraction of the portion of the ventricular wall located in the perimeter of the path pierced by the first coil. This contraction thus makes it possible to reduce the diameter of the annulus 103, performing, in whole or in part, an annuloplasty and/or a local strengthening of the annulus.

When the implant 1 is completely screwed into the ventricular wall, the push-rod 16 is removed and the wire 14 is separated from the implant 1, by traction so as to release the reversible locking whereby this wire 14 is connected to the implant 1. The wires 13 are then retracted, and the catheter 11 and then the guide wire 10 are removed (cf. figures 9 and 10).

When required by the annuloplasty to be performed, several implants are inserted side by side, in particular three implants in the example shown in figure 10.

The wire 2 can be made of a shape memory material such that the coils it forms can naturally go outside the catheter 11 during forward progress of an implant 1 outside this catheter 11.

Figure 14 shows that the wire 10 can comprise branches 10a deployable by elasticity or shape memory, which make it possible to produce a certain retention of this wire 10 in the auricular appendix 104. These branches 10a can, however, pivot from the side of the free end of the wire 10 when tension is exerted on the latter, such that the removal of this wire remains possible.

Figure 15 shows that, according to another embodiment of the invention, the wire 10 comprises deployable branches 10b, enabling anchoring of a distal portion 10c of the wire 10 in the ventricular wall, this distal portion 10c being separably connected, in particular by reversible locking, to the rest of the wire 10. This distal portion 10c remains in place after insertion of the implant 1.

Figures 16 and 17 show that the implant 1 can be inserted via the auricular side of the mitral valve. The wire is "captured" according to the so-called "lasso" technique by the loop 20a of another wire 20, introduced using a transseptal approach. The wire 10 is then pulled to allow guiding of the catheter 11 by the same transseptal approach, and placement of the implant 1 using a technique similar to that previously described.

Figure 18 shows, very diagrammatically, a helical implant 1 whereof the coils have a flat ellipsoidal shape. As is understood, each coil defines, in the implantation tissue, a path going through points 25, 26 separated from each other (cf. first angular position illustrated in broken lines); when the implant 1 is rotated a quarter turn (cf. second angular position shown in solid line), the two points 25, 26 are brought closer together, producing the contraction of the tissue located in the central perimeter of the implant.

Figures 19 to 22 illustrate an implant 1 having a cylindrical shape, i.e. having coils of a constant diameter, which is made of a shape memory material. After placement of the implant 1 by screwing (cf. figures 18 to 20), a calorific contribution takes place, in particular through the implementation of a difference in potential between the implant and the patient's body. This calorific contribution produces, via shape memory, a reduction in the diameter of the coils of the implant 1, and therefore a contraction of the portion of the wall located in the perimeter of the implant 1.

Figures 23 to 26 show another embodiment of the material for inserting the implant 1, wherein the aforementioned hollow piercing needle 29 has lateral lumens 30 arranged through its wall, and wherein the wire 10 is equipped with deployable branches 10a as described above. While the wire 10 is positioned in the needle 29 such that the branches 10a are outside the area of the lumens 30, the needle 29 is introduced through the annulus 103 and is positioned such that its lumens 30 are located beyond the wall of the annulus 103 (cf. figure 23); the wire 10 is then slid in the needle 29 to bring the branches 10a across from the lumens 30, which allow deployment of the branches 10a (cf. figure 24), then these are brought into contact with the wall of the annulus 103 (cf. figure 25); for removal of the wire 10, this wire is slid in relation to the needle 29 until it brings the branches 10a into the portion of this needle located beyond the lumens 30 from the distal side, thereby achieving bending of the branches 10a in the needle 29 and thus allowing removal thereof by sliding.

Figure 27 shows that, according to one particular embodiment of the invention, the proximal ends of two adjacent implants 1 can be connected to wires 40 engaged in a catheter 41. These wires 40 are in a relatively stiff material able to be twisted, in particular in metal. Tension exerted on the wires 40, then twisting of said wires, produces a contraction of the wall of the annulus 103 located between the implants 1, in addition to the contraction produced by the implants 1 themselves, as shown by figure 28. Each wire 40 can in particular be connected to a loop formed by the proximal end of each implant 1, before insertion of the implant.

Figures 29 and 30 show the principle of a connection element 42 having a curved shape, able to connect three implants 1. This connection element 42 can go from a first bend, which it has before implantation, to a smaller or rectilinear bend, which it has after implantation, so as to reduce the bend of the portion of the annulus 103 located between the implants.

The connection element 42 can also go, via shape memory, from an elongated shape before implantation to a shortened shape after implantation, in order to produce a contraction of the annulus 103 due to the three implants coming closer together. This connection element 42 thus forms a stiffener.

Figures 31 and 32 show that an implant 1 can comprise a front coil 1a of large diameter, and that the coils 1a of several implants 1 can be interconnected upon insertion of several consecutive implants, connecting these implants to each other.

As appears from the preceding, the invention provides an implant for treating a heart valve, in particular a mitral valve of a heart, and a material for inserting this implant, which is completely satisfactory and which makes it possible to perform either annuloplasties or strengthening of valvular annuluses, under the best possible conditions. This implant and this material consequently have determining advantages in relation to the existing techniques.

It goes without saying that the invention is not limited to the embodiment described above as an example, but that it extends to all embodiments covered by the appended claims.

CLAIMS

1 – Implant (1) for treating a heart valve, in particular a mitral valve of a heart, made up of a helically wound wire (2), characterized in that:

- it has dimensions such that it can be screwed into the wall of the annulus (103) and/or into the cardiac wall (101) adjoining this annulus (103) so that a portion of said annulus (103) and/or of said wall (101) is located in the perimeter of the implant (1); and

- the implant (1) comprises at least one first coil able, upon screwing of the implant (1), to insert itself into said wall while having a first dimension and at least one second coil having a second dimension, or adopting this second dimension after implantation, said second dimension being smaller than the first dimension such that the implant (1), once inserted, allows contraction of said wall portion located in the perimeter of this implant (1).

2 – Implant (1) according to claim 1, characterized in that said first coil(s) are located, in the direction of screwing of the implant (1), in front of said second coil(s).

3 – Implant (1) according to claim 1 or claim 2, characterized in that its coils have a non-circular shape, in particular oval or elliptical.

4 – Implant (1) according to one of claims 1 to 3, characterized in that the wire (2) constituting the implant (1) is in a shape memory material, defining, in a first state, coils having said first dimension and, in a second state, coils having said second dimension.

5 – Implant (1) according to one of claims 1 to 4, characterized in that the front end (5) of the wire (2) which constitutes it is pointed or sharp.

6 – Implant (1) according to one of claims 1 to 5, characterized in that the wire which constitutes it has a same structure along its entire length.

7 – Implant (1) according to one of claims 1 to 5, characterized in that the wire constituting it comprises portions in a first material and portions in a second material different from the first material.

8 – Implant (1) according to one of claims 1 to 7, characterized in that the wire which constitutes it comprises portions having different structures, for example

solid, resistant portions and portions having a thinner cross-section able to break in case of exertion on the implant of stresses directed radially outwardly.

9 – Implant (1) according to one of claims 1 to 8, characterized in that it comprises radiopaque markers enabling its visualization through the body of the patient, in particular markers making it possible to visualize the angular orientation of the implant when the latter comprises non-circular coils.

10 – Implant (1) according to one of claims 1 to 9, characterized in that it comprises means ensuring its anchoring in the tissue with regard to screwing or unscrewing.

11 – Material including the implant according to one of claims 1 to 10, characterized in that it comprises means (40) making it possible to connect at least two adjacent implants (1) inserted in an annulus (103), so as to achieve a contraction of the wall of the annulus (103) located between the implants (1), in addition to the contraction done by the implants (1) themselves.

12 – Material according to claim 11, characterized in that said means comprise wires (40) in a material able to be twisted, in particular in a metallic material, connected to the proximal parts of the implants (1), these wires (40) being engaged in a same catheter (41) then being twisted to bring the two implants (1) closer together.

13 – Material including the implant according to one of claims 1 to 10, characterized in that it comprises curved connection means able to connect at least two implants, these connection means being able to go from a first bend, which they have before implantation, to a smaller or rectilinear bend, which they have after implantation.

14 – Material including the implant according to one of claims 1 to 10, characterized in that it comprises connection means able to connect at least two implants, these connection means being able to go, via shape memory, from an elongated shape before implantation to a shortened shape after implantation, in order to achieve a contraction of the valvular annulus due to the implants being brought closer together.

15 – Material for inserting the implant (1) according to one of claims 1 to 10, or the material including this implant according to one of claims 11 to 14, characterized in that it includes at least one catheter (11) able to deliver the implant

(1), means (16) for moving the implant (1) longitudinally in relation to this catheter (11) and means (14, 15, 16) for driving the implant (1) in rotation along the axis of the implant (1).

16 – Material according to claim 15, characterized in that the longitudinal movement means comprise a push-rod (16) slidingly engaged in the catheter (11).

17 – Material according to claim 15 or claim 16, characterized in that the means for driving in rotation comprise a wire (14) connected separably to the rear end of the implant (1).

18 – Percutaneous intervention method for performing the treatment of a heart valve, in particular to perform an annuloplasty, i.e. a reduction of a distension of the valvular annulus (103), or a strengthening of the annulus (103) of a normal valve, characterized in that it comprises steps consisting of:

- using the implant (1) according to one of claims 1 to 10 and the material according to one of claims 15 to 17;

- bringing the distal opening of the catheter (11) comprised by the material across from the area designed to receive the implant (1);

- moving the implant (1) forward in relation to the catheter (11) while driving this implant (1) in rotation along its axis, in order to achieve screwing of the implant (1) into the annulus (103) of the valve to be treated and/or the cardiac wall adjoining this annulus (103);

- if necessary, repeating the preceding steps so as to insert as many implants (1) as necessary to perform the desired annuloplasty and/or strengthening of the annulus (103).

19 – Intervention method according to claim 18, characterized in that the step consisting of bringing the distal opening of the catheter (11) across from the area designed to receive the implant (1) is done by approaching the valve from one or the other of the sides of this valve, in particular, involving the treatment of a mitral valve, either using a ventricular approach or an auricular approach.

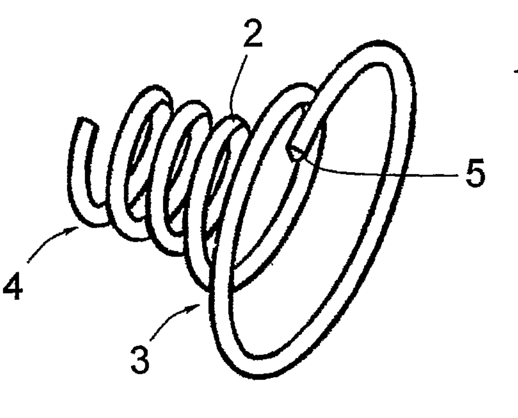

FIG. 1

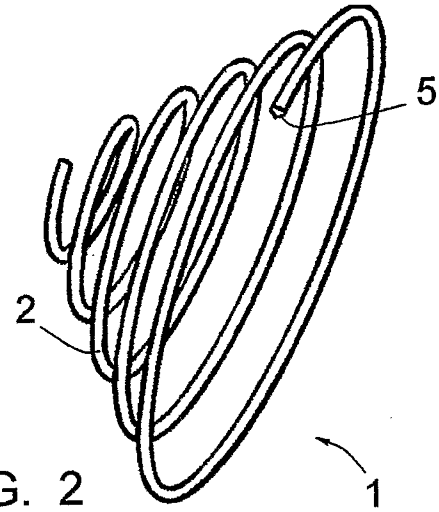

FIG. 2

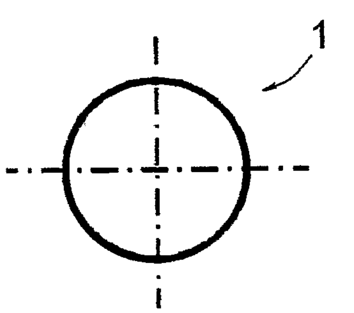

FIG. 3

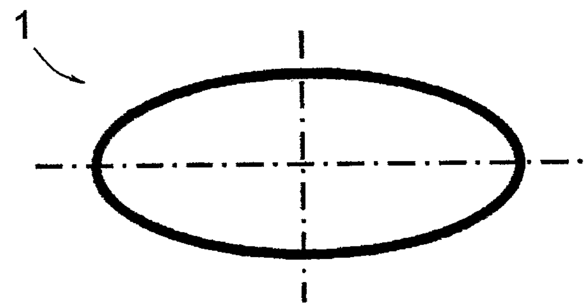

FIG. 4

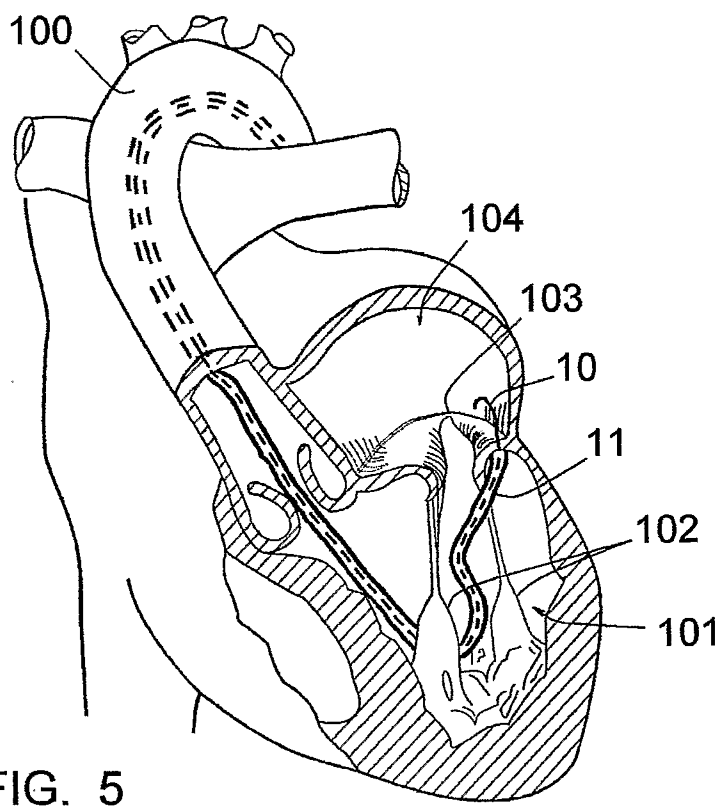

FIG. 5

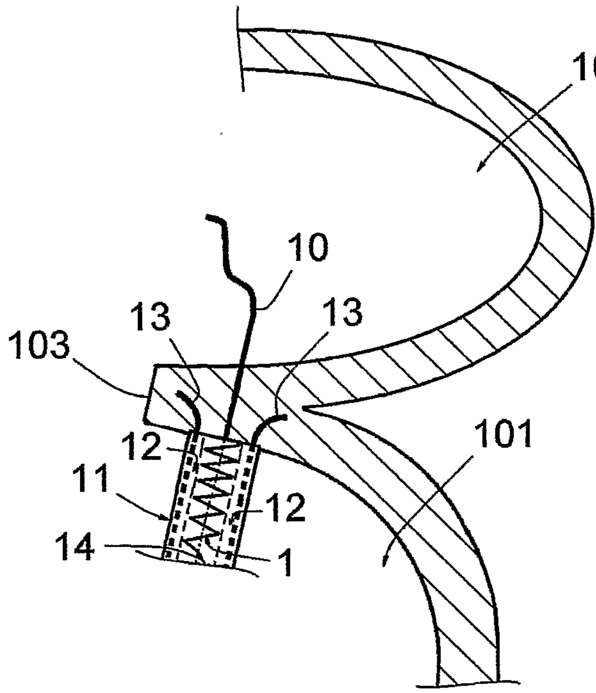

FIG. 6

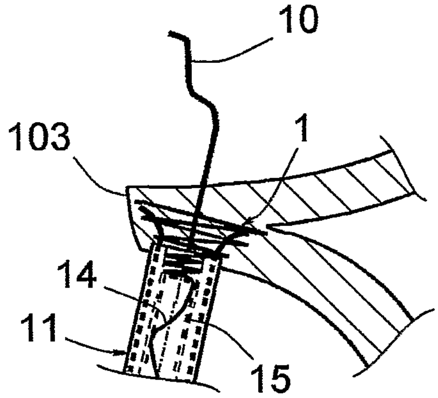

FIG. 7

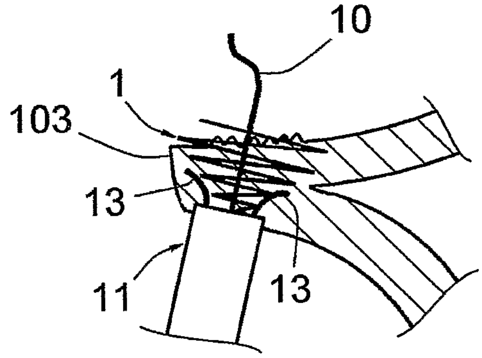

FIG. 8

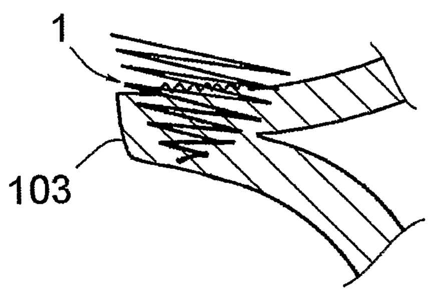

FIG. 9

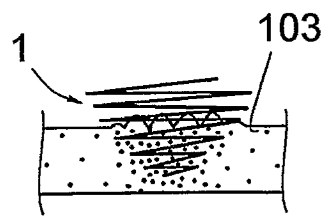

FIG. 10

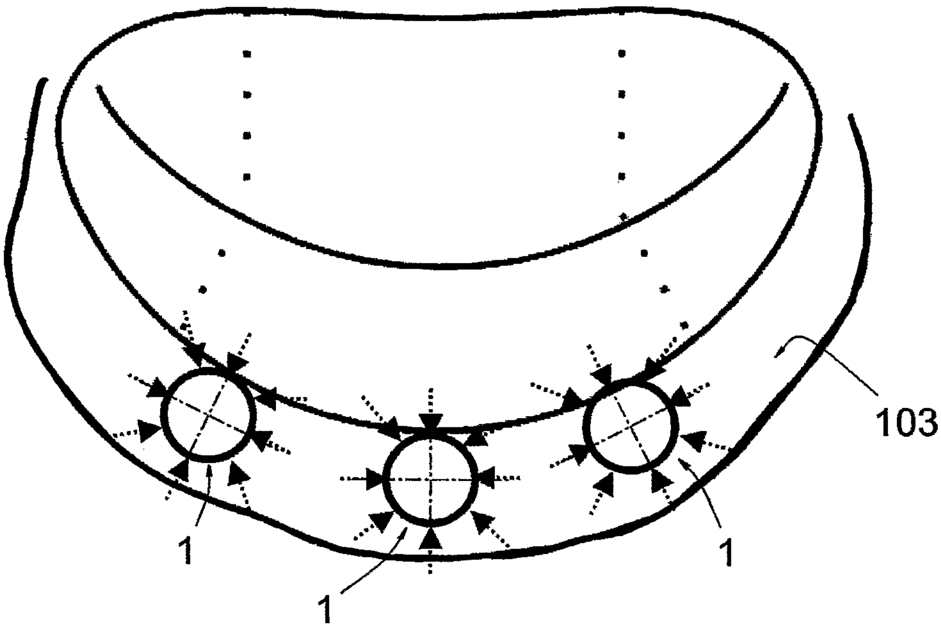

FIG. 11

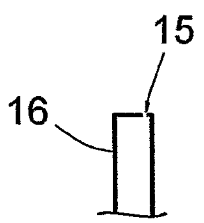

FIG. 12

FIG. 13

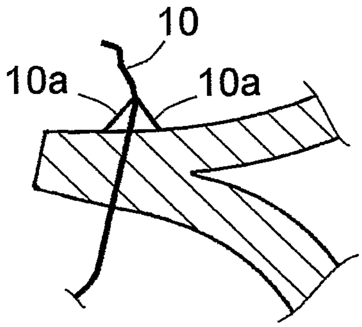

FIG. 14

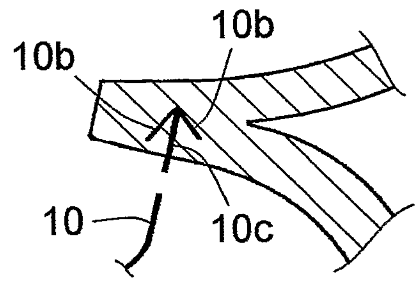

FIG. 15

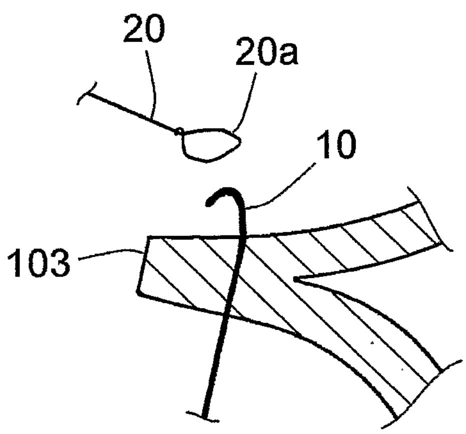

FIG. 16

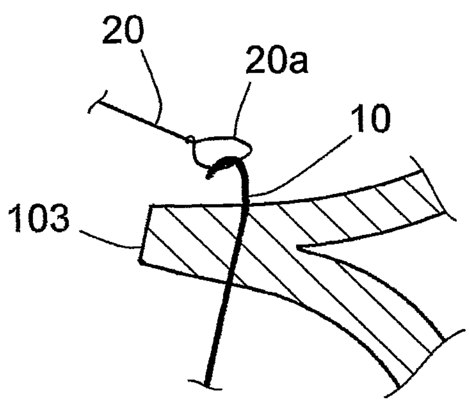

FIG. 17

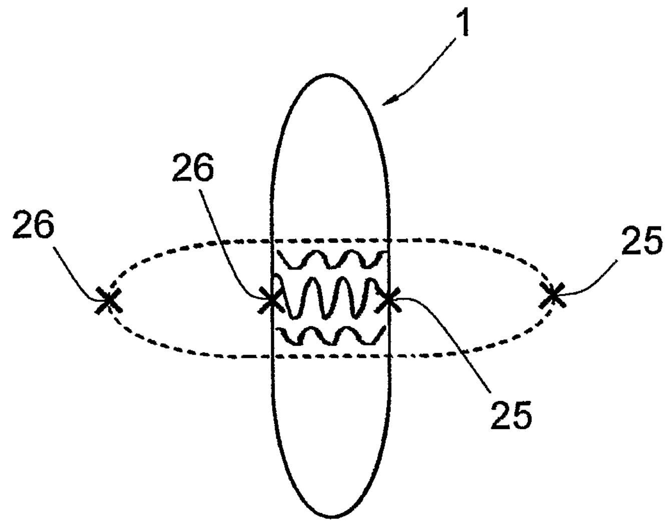

FIG. 18

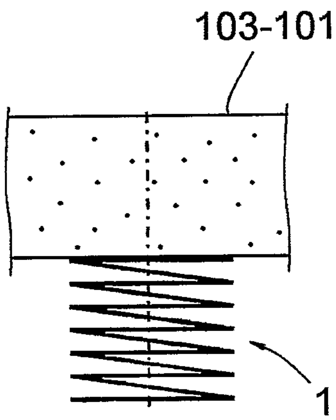

FIG. 19

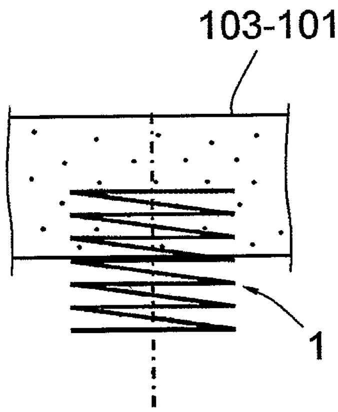

FIG. 20

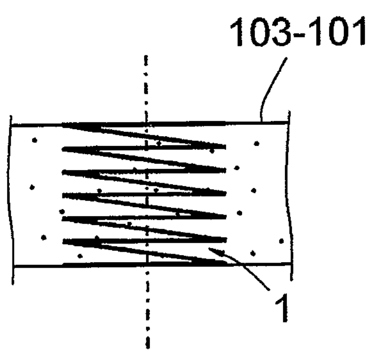

FIG. 21

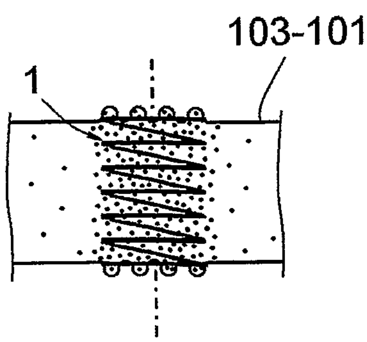

FIG. 22

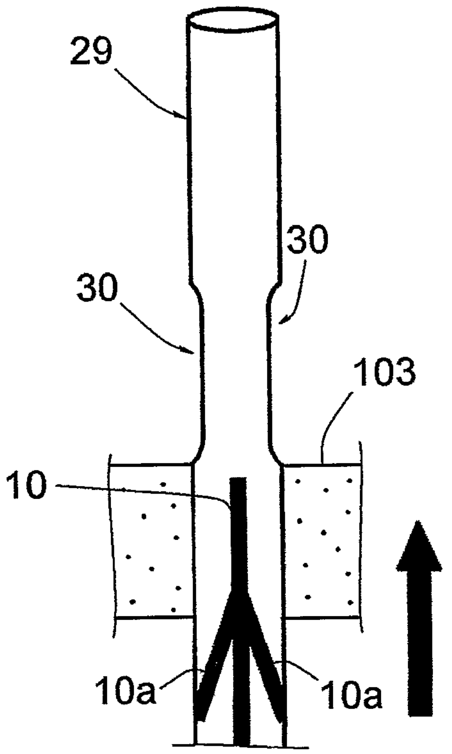

FIG. 23

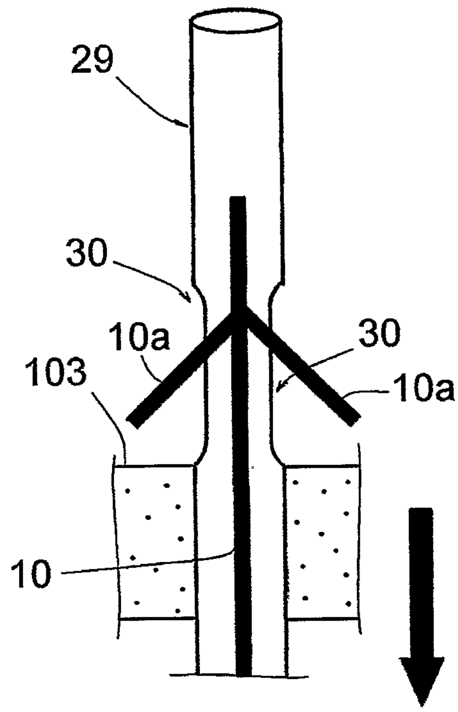

FIG. 24

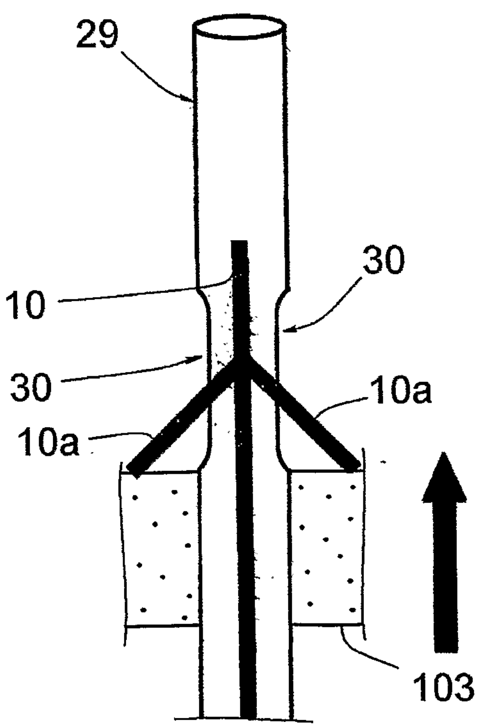

FIG. 25

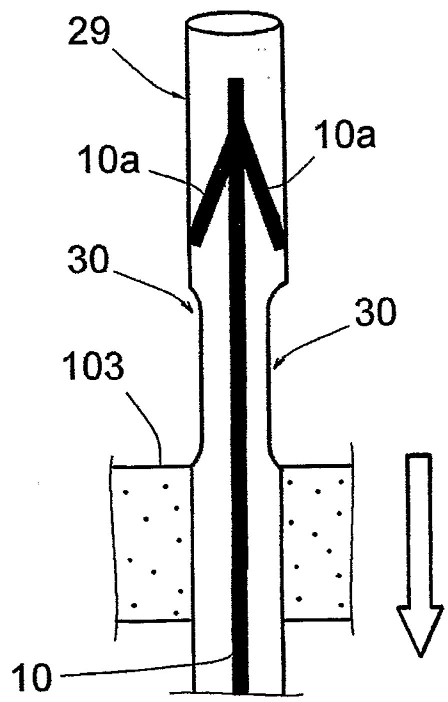

FIG. 26

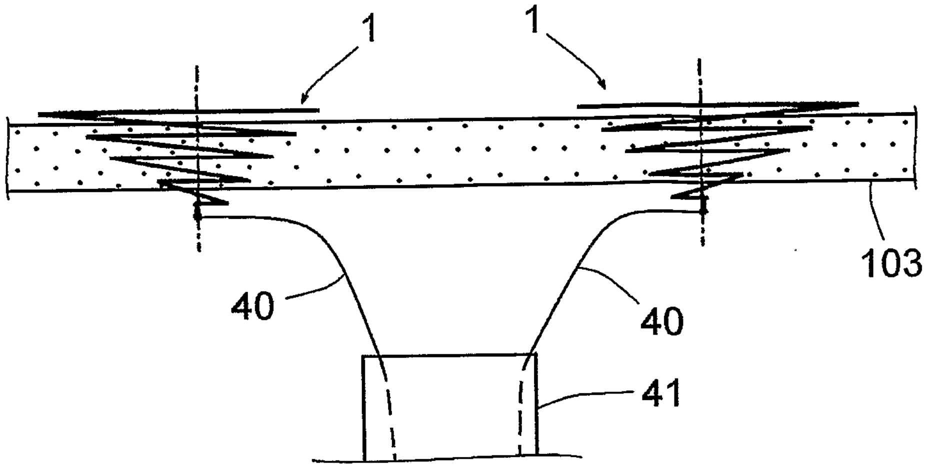

FIG. 27

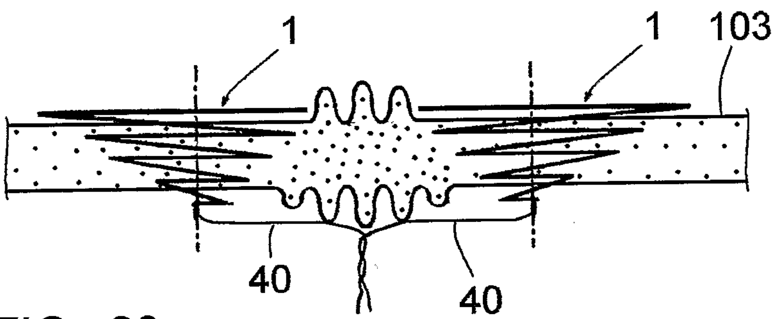

FIG. 28

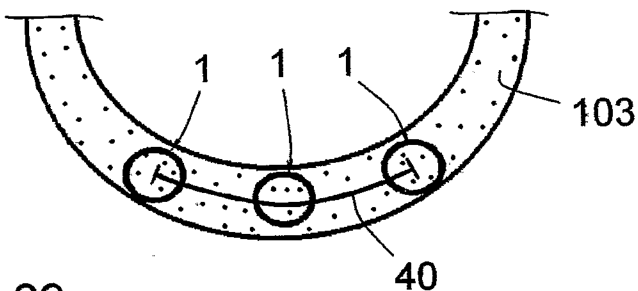

FIG. 29

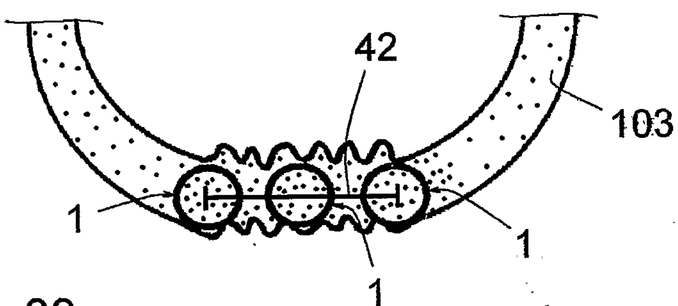

FIG. 30

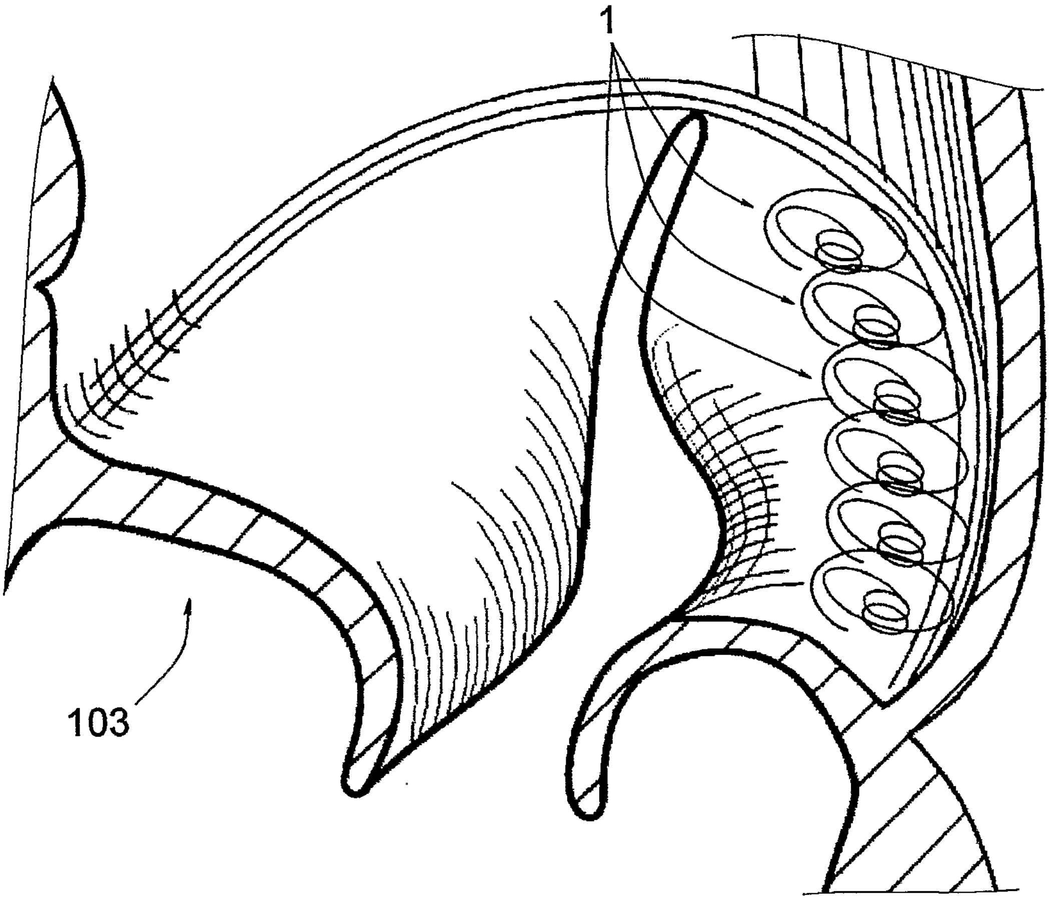

FIG. 31

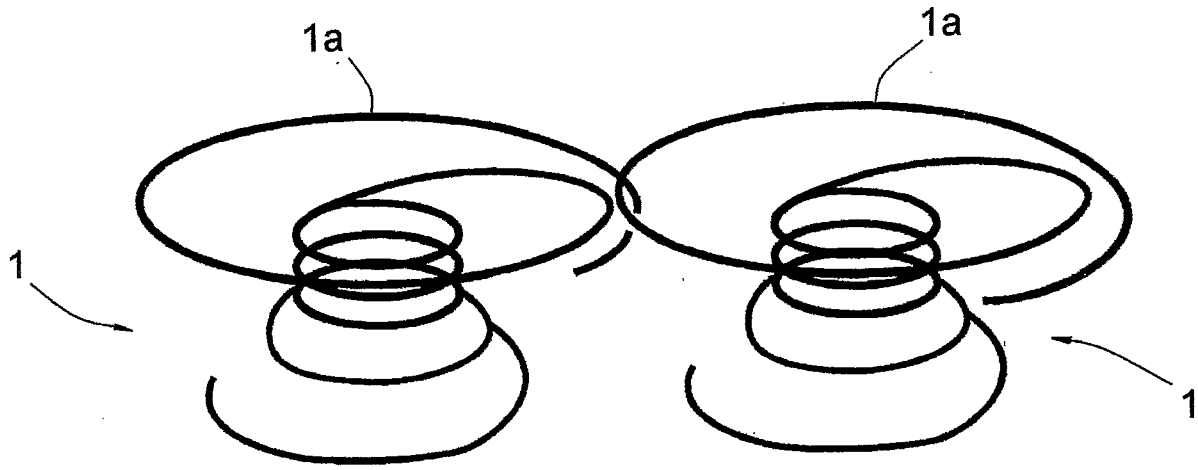

FIG. 32