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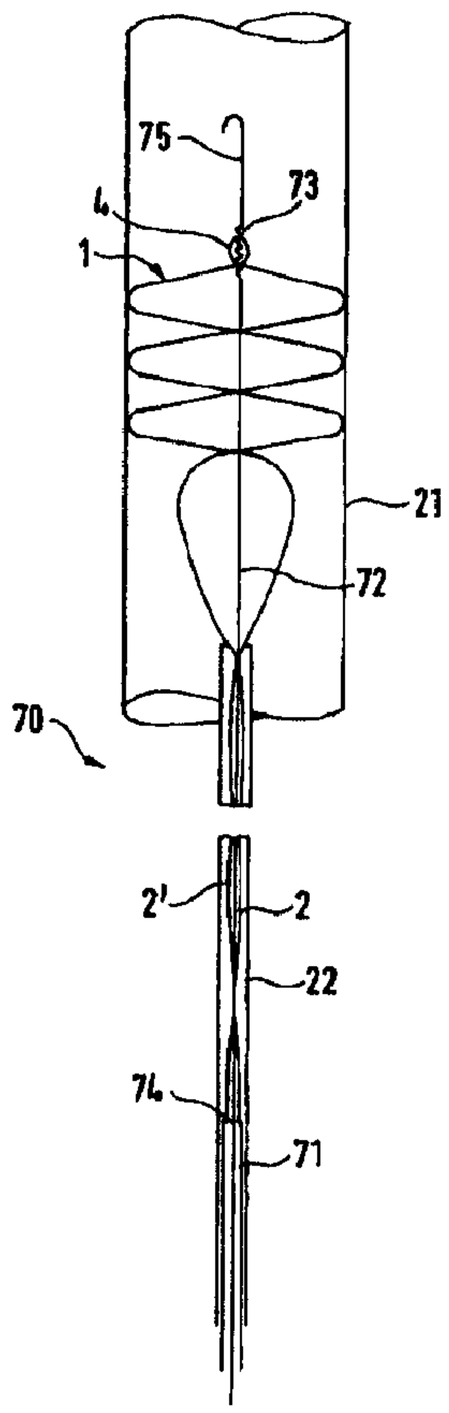

(57) Abrégé/Abstract:
A known method for treating pathological body vessels is the implantation of stents (1) as an extended filament (2), by means of a catheter (22), which springs into a given form only once at the implantation site, as a result of its thermo-memory property or its elasticity. The invention relates to a new kind of stent (1), created in order to improve the flexibility and stability of the stent. This is

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achieved in that the stent filament or stent filaments (2, 2') are present in the form of at least two opposed spirals (3, 3'). The filament (2) consists of a material with high elasticity or with thermo-memory properties. The stent (1) can be covered with a structure made of pieces of fabric and/or fibres, and serves in this way as a stent graft. The new stent demonstrates high stability and flexibility. The stent can be introduced into a body vessel by means of a lumen, which essentially corresponds to the outside diameter of the filaments (2, 2') forming the stent (1), by means of catheter (22), and expands in the point of destination to a large-lumen tube-shaped implant.

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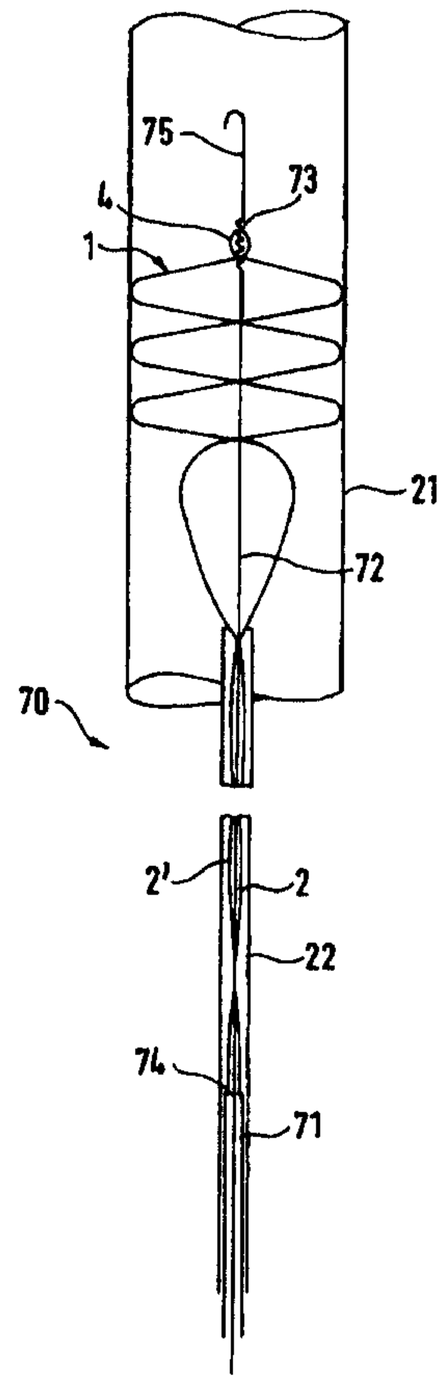
(54) Title: STENT FOR TREATING PATHOLOGICAL BODY VESSELS

(54) Bezeichnung: STENT ZUR BEHANDLUNG PATHOLOGISCHER KÖRPERGEFÄSSE

(57) Abstract

A known method for treating pathological body vessels is the implantation of stents (1) as an extended filament (2), by means of a catheter (22), which springs into a given form only once at the implantation site, as a result of its thermo–memory property or its elasticity. The invention relates to a new kind of stent (1), created in order to improve the flexibility and stability of the stent. This is achieved in that the stent filament or stent filaments (2, 2') are present in the form of at least two opposed spirals (3, 3'). The filament (2) consists of a material with high elasticity or with thermo–memory properties. The stent (1) can be covered with a structure made of pieces of fabric and/or fibres, and serves in this way as a stent graft. The new stent demonstrates high stability and flexibility. The stent can be introduced into a body vessel by means of a lumen, which essentially corresponds to the outside diameter of the filaments (2, 2') forming the stent (1), by means of catheter (22), and expands in the point of destination to a large–lumen tube–shaped implant.



(57) Zusammenfassung

Zur Behandlung pathologischer Körpergefäße ist es bekannt, Stents (1) durch einen Katheter (22) als langgestrecktes Filament (2) zu implantieren, der erst am Implantationsort infolge seiner Thermo–Memory–Eigenschaft oder seiner Elastizität in eine vorgegebene Form springt. Zur Verbesserung der Flexibilität und Stabilität des Stents wird ein neuartiger Stent (1) dadurch geschaffen, daß das oder die Stentfilamente (2, 2') in der Form wenigstens zweier gegenläufiger Wendeln (3, 3') vorliegen. Das Filament (2) besteht dabei aus einem Material hoher Elastizität oder mit Thermo–Memory–Eigenschaften. Der Stent (1) ist mit einer Struktur aus Gewebeteilen und/oder Fasern ummantelbar und dient somit als Stentgraft. Der neue Stent weist eine hohe Stabilität und Flexibilität auf. Der Stent kann durch ein Lumen, das im wesentlichen dem Außendurchmesser der den Stent (1) bildenden Filamente (2, 2') entspricht, durch einen Katheter (22) in ein Körpergefäß eingeführt werden und erweitert sich am Bestimmungsort zu einem großlumigen röhrenförmigen Implantat.

Stent for treating pathological body vessels

Field of the Invention

The invention relates to a stent which can be introduced into the body vessel in the form of at least two elongated filaments by means of an implantation device, and which assumes its preferred shape only at the site of implantation after the implantation has been carried out.

Related Art

It is known that, in order to treat pathological body vessels and blood vessels, spiral stents made of metal or plastic may be introduced into such diseased body vessels .

Such treatments are considered for pathological occlusions of vessels or for aneurysms, particularly of the aorta. The implantation of such vascular prostheses is made difficult by the considerable diameter of these prostheses. For the most part, the vascular prostheses have to be surgically implanted by opening up the vessel and subsequently closing it by means of a vascular suture. When treating an aortic aneurysm, stents are introduced via the pelvic arteries. This treatment is made difficult or is totally prevented by stenoses that occur frequently in combination with aortic aneurysms and by the serpentine course of the pelvic arteries.

In the cases mentioned, but also when treating smaller vessels, such as intracranial vessels, it is advantageous to use stents which can be widened from a small diameter for implantation purposes to a larger diameter at the implantation site. Accordingly, provision is made to implant balloon-expandable and self-expanding stents, using a suitable catheter, in the vessels to be treated. However, so far, the subject stents still do not satisfy the technical requirements for problem-free use.

The so-called IN stent, for example, is an elastic spiral which is held at a small diameter by the catheter while it is being introduced into the body vessel; it is then released from the catheter by means of a special mechanism at the site of implantation where it expands to its in-use diameter.

The disadvantage in this case is that the diameter of the spiral stent in the expanded state is at most double that in the inserted state, so that relatively large puncture openings are required to insert this type of stent.

In this connection, the use of a thermal-memory wire has already been described in the paper titled "Transluminally placed coil spring endarterial tube grafts", Invest. Radiol. (1969) No. 4, pages 329 ff, by Charles Dotter.

Thermal-memory wires are mostly Nitinol wires, i.e. nickel-titanium alloys, which are given a predetermined shape at temperatures between 400° and 500°C and which retain this shape down to a certain transformation temperature below body temperature.

The phrase "thermal-memory property" is understood to mean that these wires lose their previous shape and elasticity when exposed to appropriate further cooling, e.g. using ice-cold water, and then become freely movable and flexible, elongated wires. As soon as such a wire is warmed up again to approximately body temperature, it springs back fully elastically into the spatial shape imprinted in it during the heat treatment phase.

Charles Dotter has proposed implanting a spiral stent made from cooled thermal-memory wire in elongated form which subsequently, because of its described thermal-memory property, springs into the desired spiral and prosthetic shape at the implantation site.

It has been shown that, in their preferred state, such simple coiled stents have insufficient stability and in addition are difficult to insert and position precisely.

A stent is known from WO 94/03127 in which several wire filaments are introduced in elongated form and then, in their preferred state, assume an undulating shape that closely conforms to the wall of the vessel, the undulating lines of in each case two filaments being formed in such a manner that a network comprising approximately oval elements is formed. The stability of this

network can be further increased by joining together opposite undulating lines at the points where they are closest to each other.

It is a disadvantage of this kind of reticulately structured stent that the implantation of such a complicated structure creates considerable difficulties, especially in greatly curved vessels. In addition, the construction of such a stent, consisting of a plurality of single filaments, requires a catheter with a relatively wide insertion diameter. Furthermore, this above-described stent has, in each case, only one predetermined diameter in the expanded state. It is therefore difficult to adapt the stent diameter to the diameter of the artery to be treated.

From WO 95/18585, a stent is known in which the filaments have the form of spiral coils running in the same direction of rotation. In order to create areas of differing stiffness, the coils are designed in certain areas with varying degrees of pitch in the longitudinal direction of the stent. Such stents are, however, relatively unstable and are difficult to handle because the stent tends to become jammed inside the pathological body vessel when it is being implanted.

US Patent 5, 116, 365 discloses a balloon-inflatable stent whose filaments are clearly not of permanently elastic design. In the longitudinal direction of the stent, the filaments have the form of zig-zag-shaped intertwined strips which are coiled in serpentine fashion to give the necessary elasticity. This creates a reticulate structure composed of approximately diamond-shaped elements. Such stents are difficult to handle.

From WO 94/00179 a stent is known in which the filaments are arranged in the form of zigzag loop structures along the length of the stent.

Although the special arrangement and the form of the filament structures impart greater stability to the implanted stent when it assumes its preferred shape, such stents nevertheless have only one predetermined diameter in the

expanded state. This can lead to considerable impairment of the blood flow in body vessels having, in contrast, overall or partially smaller vessel diameters.

WO 92/05829 discloses a stent having a woven form which is only temporarily insertable and therefore must be removed again after a certain dwell time. This stent is formed from three or more individual, elongated filaments, which in the implanted state form oppositely oriented spiral structures in the longitudinal direction of the stent. Because of the design, the two ends of each of the filaments that make up the stent lie in the area of the central longitudinal axis of the stent, where they are attached by means of a flexible sleeve to a rod- or tube-shaped catheter inside the stent. This can considerably influence the blood flow.

Summary of the Invention

It is therefore the purpose of the present invention to create a stent of the aforementioned type for the aforementioned purpose, the stent being characterized by a high degree of stability as well as simple handling during implantation, and also possessing a large expansion rate, i.e. a particularly high ratio of the stent diameter in the expanded state to the stent diameter in the introduced state.

This task is solved by a stent with at least two of the filaments (2, 2') present over at least part of the length of the stent (1) in the form of oppositely oriented spirals (3, 3').

Thus, in its preferred state, the stent according to the invention consists of at least two spirals arranged in opposite directions of rotation to one another, and it has the external shape of a tube.

Such a double-spiral stent is inserted with the filaments in the elongated state, i.e. having an almost one-dimensional structure.

A stent formed in this manner possesses a high degree of stability combined with a high degree of flexibility. The pitches of the individual spiral loops can be greatly varied over the entire length of the stent. This makes it possible, in particular, to place the stent in greatly curved body vessels without having to accept any impairment of the stability of the stent or any reduction in the lumen of the body vessel, not even just in certain sections of the vessel. The overall length of the stent body can also be varied due to the variability of the pitches of the individual loops. In this way, for example, the stent can be better anchored within the body vessel. In addition, the load-bearing or support capacity of the stent can be variously adapted in each case to the vessel when treating vascular disorders, such as aneurysms. For example, low-pitch and therefore high-density spiral loops are required at the ends of an aneurysm stent in order to anchor the stent at these points, while in the region of the aneurysm itself fewer spiral loops are required.

Particularly non-damaging and simple implantation of the stent is possible especially if the filament is made from a thermal-memory wire. In this connection, the use of Nitinol wires is particularly recommended. However, plastic filaments with suitable thermal-memory properties can also be used. Instead of the filament made from thermal-memory wire, it is also possible to select highly elastic to super-elastic wires for use as the filaments; because of their special elastic properties, these filaments attain their preferred spiral shape at the implantation site. Such a filament may also be manufactured from Nitinol, from stainless steel or from suitable plastics.

Advantageously, two filaments each forming a spiral are produced from one single filament wire having, for example, at the distal end of the stent a bend, an arcuate section or a loop, such that two oppositely oriented spirals can be formed. Such a configuration is extremely stable.

Instead of producing the double-spiral structure of the stent according to the invention from a filament wire, which can be appropriately bent in the shape of oppositely oriented spirals, it is also possible to cut the double-spiral

structure of the stent from a tubular workpiece. The cutting can be done very efficiently by means of a laser. The particular advantage of this configuration is that the oppositely oriented spirals are already joined to each other at their cross-over points, thereby making it unnecessary to use any additional means of connection.

A similar stabilizing effect of the stent can be achieved by joining together two spirals, constructed from single filaments, for example at the distal end of the stent. This joining can be accomplished, for example, by glueing, soldering or welding the two stent wires or, however, a connecting sleeve may be used that engages over the two stent wires and thus produces a connection; said sleeve permits limited axial displacement of the stent wires but prevents twisting of the stent wires relative to each other. This also improves the flexibility of the stent. A corresponding connection may also be present at the proximal end of the stent.

Advantageously, these points of connection between the two spirals are located on the outer periphery, i.e. at the surface, of the tube-shaped stent. This minimizes as far as possible any disruption in the blood flow through the body vessel. The connection points are preferably bent radially outwards so that they cannot in any way project into the lumen. In particular when the vessel follows a curved path, the ends of the stent in such an embodiment adapt themselves to the curved path of the body vessel.

In order to increase the stability of the stent still further, the oppositely oriented spirals are joined to each other at least partially at the points where the spirals cross over each other. A particularly advantageous connection is produced by using threads having good biological compatibility, such as nylon threads, which are attached to one of the spirals and possess loops at predetermined points through which the respective other spiral is passed. Such a configuration permits the double spiral to be deployed, without any problems, during the implantation process. In order to avoid friction between the spirals, or between the spirals and the body tissue, which

could lead to wear and tear of the filaments or to irritation of the tissue, the spiral loops should be firmly joined together with another such that, in the preferred state, the possibility of the spirals moving in relation to each other is reduced to a minimum.

In one embodiment the stent possesses three or more filaments. While two of the filaments are present in the stent in the above described manner in their preferred shape as oppositely oriented spirals of preferably identical pitch, the other, also spiral-shaped, filaments run with a different pitch than the two oppositely oriented spirals. As a result, the third filament runs, or the following filaments run, at least partially in the gaps created by the oppositely oriented double spirals. The overall stability of the stent is increased thereby and in addition a substantially constant lumen is maintained over the entire length of the stent.

Although the structure of the stent formed by two oppositely oriented spirals is extremely stable and flexible, it may on occasion be advantageous if part of the overall length of the stent consists of a double spiral in which the spirals are not oppositely oriented but rotate in the same direction. Thus, in this area there are no cross-overs of the filaments. In addition, the stent is even more flexible in certain sections, and this is advantageous, for example, when it is implanted in highly curved vessels.

In another embodiment better spring action is achieved in the longitudinal direction of the stent. Such a stent not only has a higher load-bearing and support capacity, but it is also more compatible with the body, especially when it is implanted in the curved or flexed regions of vessels.

An advantageous further development of the embodiment according to claim 13 is obtained if, in each case, two filaments possess similar, oppositely oriented arcuate sections arranged at least over part of the length of the stent.

Advantageously, oppositely oriented arcuate sections of two filaments are joined together. The arcuate sections may be hooked into one another in the manner of a wire mesh fence, thereby achieving higher flexibility and stability of the stent. An especially flexible but nevertheless stable connection is obtained by textile threads which are firmly attached to the one filament and possess loops that receive the respective other filament. Such an embodiment in particular facilitates manipulation when the stent is inserted in the form of elongated filaments. At the same time, such a connection permits axial movement of the filaments relative to each other, and this in turn is advantageous in highly curved body vessels. As an alternative to the flexible connection of the arcs with each other, it is also possible to have a rigid connection using, for example, sleeve connectors that engage over both arcs, or the connection may be made by welding, soldering or glueing. A combination of sleeves and the other cited means of fastening is also conceivable. When the arcuate sections are rigidly connected together, the introduction radius through the catheter can be kept particularly small.

In a particularly advantageous embodiment
the filaments of the stent alternatingly have the form of arcs and
spirals and are offset in relation to each other so that in each case one arc intersects with a spiral loop. This results in a nearly right-angled cross-over, thus further improving the stability of the stent. Preferably one of the filaments at the preferred cross-over point possesses a small recess in which the corresponding filament may be received. In their preferred state, the corresponding filaments engage at this point, thereby still further increasing the stability.

Advantageously, in its preferred state, the cross section of the stent is matched to the body vessel for which it is provided. It may, for example, be advantageous if at least sections of the stent are provided with an oval or elliptical lumen. A broader lumen is required, for example, for the proximal part of the stent in the A. carotis communis or in the bulb of the A. carotis interna,

while the distal end must have a smaller diameter because the cross section of the artery in general is narrower here.

In a further embodiment, the stent is used as a double stent. In this case, only one section of the stent possesses a single tubular shape of the type described above. In a second section, on the other hand, the stent possesses two lumina, which are each supported by at least one spiral filament and which are in partial contact with each other. Thus a double stent is formed over at least part of the length of the stent. The lumina of the two auxiliary stents may be oval in shape, as described above, or they may have the cross sectional shapes of two mirror-image "D's". At their points of contact, the two auxiliary stents may also be joined together by threads, in the manner described above, said threads being attached to at least one of the filaments and possessing loops which receive the respective other filament. It is also possible for the two spirals of the double stent to be made of filaments arranged in such a manner that the loops, seen in cross section, have the form of a figure eight, i.e. they cross over each other. In such an embodiment it is not necessary to attach the two auxiliary stents to one another.

The stents having the characteristics described above are covered,

with a deformable membrane sheath on the outer or inner side of the double-spiral structure. The membrane is attached at the respective ends of the stent and in the preferred, i.e. expanded, state of the stent it is not subject to longitudinal tensile load. If the stent is stretched in length, the membrane is correspondingly stretchable. Highly elastic plastic, silicone or latex are, for example, advantageous materials from which to produce such a membrane. However, as an alternative to elastically deformable membrane sheaths, it is also possible to use a knitted fabric, the meshes of which can be converted, upon implantation of the stent, from an introductory shape, in which the threads of the textile fabric run substantially parallel to the stent axis, to an expanded shape, in which the mesh-forming threads run substantially perpendicular to each other. The threads of such a knitted fabric may also be textured, i.e. may possess an expandable, spiral-shaped structure.

It is particularly advantageous to use textile material such as, for example, elastic fabric or polytetrafluoroethylene (PTFE), which can also be appropriately stretched. In this case, the open meshes of the fabric would be quickly closed by the formation of thrombi, so that in this case as well a closed wall is formed.

In order to prevent the textile fabric from intruding between the filaments of the stent into the interior of the stent when the stent is expanded, preferably intersecting metal threads are worked into the fabric structure of the textile membrane sheath and the threads prevent the textile from protruding into the region between the spiral elements of the stent.

An equally advantageous possibility of providing a stent with a sheath is also disclosed.

In one embodiment the stent has the form of a wire loop skeleton whose individual double-spiral loops are shielded from the wall of the vessel by textile structures or fibres attached to the filaments. The body of the stent is thus only partially formed by the filament and the rest is made up of fibres or fabric sections.

Using fabric structures or fibres to shield the filaments from the vessel wall considerably improves the compatibility of the stent with the body. Such a stent thus corresponds to a stent graft. However, one decisive advantage of this embodiment is that, in contrast to the previously known wire stents having wire loops in contact with one another, in the area of the fabric and fibre sections the walls of the stent body possess membrane properties, i.e. for example they are capable of diffusion. The walls of the vessel can thus continue to be supplied by way of diffusion. In addition, it is possible to locally administer any medication that is required by coating the novel wall of the stent. This reduces the risk of any hyperplasia of the intima or the risk of any other neoplastic growth in the walls of the vessel to be treated. Another advantage is that increased accumulation of connective tissue

cells, or increased formation of thrombi, results in the area of the fabric or fibre sections of the stent wall. In contrast to the known embolization coils for sealing vessels according to Gianturco, the stent according to the invention forms, as it were, a tube provided with fibres which leaves the volume of the vessel open. Because of the accumulations of cells described above, a biological wall gradually forms as a result of the thrombogenicity of the fabric structure or of the fibres. Finally, it is possible to prepare the fibres in such a manner that, following implantation, they can deliver, for example, thrombogenic medications, in order to achieve the most rapid possible sealing of the walls of the stent body.

It is particularly advantageous if the free ends of the fabric structures and/or fibres proceeding from different spirals and/or arcuate segments come at least partially into contact with each other. In this way, the wire filament is surrounded by a sheath of fibres and/or fabric structures. Having regard to the described accumulation of cells, this favours the formation of a biological wall because of the thrombogenicity of the fabric structure or of the fibres. In this way it is possible, for example, to shut off aneurysms from the normal blood flow, thereby effectively preventing or at least considerably reducing the risk of the aneurysm rupturing. The treatment of aneurysms is particularly advantageous, especially when these are present in the infrarenal section of the Aorta abdominalis, but also in the case of smaller intracranial aneurysms.

The stent can be manufactured without using adhesives which are foreign to the body and which furthermore are of dubious stability and compatibility with the body, in such a manner that at least one filament is sheathed and/or wrapped, with the fabric structures or fibres being included. This sheathing or wrapping can be carried out using another textile or thread. No additional fastening of the fabric structures or fibres is necessary.

In a further embodiment of the invention, the fabric structures or projecting fibres can be simply fastened by producing a filament from several intertwined filaments, whereby the fabric structures and fibres are held within the

intertwinings of the individual filaments. The fabric structures and/or fibres are thus passed through openings that are present between the intertwined sub-filaments. Instead of this, it is also possible to provide openings in a filament through which the fabric structures and/or fibres are pulled. At least in such an embodiment the filament possesses advantageously a rectangular cross section. In these embodiments, as well, it is not necessary to use additional adhesive or other means of attachment for the fabric structures or fibres.

Advantageously, the fabric structures and/or fibres extending radially away from a filament differ in length in certain sections and/or depending on the radial direction, in accordance with what is needed for the respective body vessel.

In a particularly advantageous embodiment, the
fabric structures and/or the fibres are fastened in such a way to the filaments that their free ends at least approximately touch, with an undulating boundary line being formed between them. When the transition occurs to the preferred state, the sheath of fabric structures and/or fibres is thus particularly advantageously adapted to the spiral structures.

A particularly dense and solid stent sheath is formed when the fabric structures and/or the fibres between the individual, adjacent spirals and/or arcuate segments formed from the filaments at least partially overlap.

The fabric structures of the stent may
be manufactured from a textile as well as a metal structure in order to produce diffusion-capable membrane sections. When textile fabrics are used, the membrane sections possess smaller pores and when metal fabrics are used they possess larger pores. In the case of small-pored fabric sections, the rate of thrombus formation and the rate at which the introduced structures are organized is accelerated. On the other hand, metal fabric structures possess greater transverse stability. It may, however, be sensible to combine metal fabric structures with textile fabric structures

The transverse stability of such a stent can also be increased by cutting fringe-like elements on the fabric structures, at least in sections thereof. When the fringes are of appropriate length, the fabric structures can overlap and interlock with a stiffening and sealing effect.

The same goal can also be achieved by providing the fabric structures with bonding means, preferably a hook-and-loop fastener, to join the overlapping fabric structures. In addition, the use of appropriate hook-and-loop fasteners ensures that the elongated filaments attain their spiral shapes at the implantation site. This bonding effect can also be achieved by arranging on the filaments thin strips of fabric having alternating hooks and loops in the manner of hook-and-loop fastener strips.

The cross section of the fabric structures used
decreases towards the outside with increasing distance from the respective filament, thereby ensuring that the stent retains a substantially constant outer diameter also in the area of the overlaps. Advantageously, the fabric structure and/or the fibres consists/consist of an elastic material. This ensures that, once they have passed through the catheter, the fibres automatically right themselves into their intended position, extending radially away from the filament. The fibres may be joined with the filament by means of a mechanically producible seam. This permits extremely simple manufacture of such stents.

In order to seal the stent optimally with respect to the body vessel, it is advantageous, for example in connection with treating aneurysms, to dimension the length of the fibres in such a way that these interwoven fibres preferably project into the corresponding vascular dilatation, thereby promoting increased formation of thrombi in said vascular dilatation. It is also conceivable for the fibres to project preferably radially into the interior of the stent in order to form an anastomosis with a possibly underlying stent. In this embodiment, the connection with a second inserted stent is better sealed.

The implantation of a stent and its positionally correct placement can be simplified by providing at least one filament with special markings which, for example, make it easier to observe the stent by TV-fluoroscopic means. However, other diagnostic methods are conceivable, such as magnetic resonance tomography or ultrasound.

As an alternative to the above-mentioned embodiments, in which the inner area of the stent is enclosed by a double-spiral structure, the stent according to claim 38 possesses a double-spiral structure in which substantially parallel-oriented filament wires form oppositely spiralling loops at predetermined spacings along the length of the stent. The outer radius of the stent is determined by the radii of the loops. During implantation, the loops lie extended along the otherwise longitudinally extended stent body. At the implantation site, the loops, which are made preferably of superelastic or thermal-memory material, stand up and assume their implanted form. As in the previously described embodiments, this stent may also be sheathed in a membrane of elastic material and the filaments of the stent may again be joined together with each other by sleeves.

It is particularly advantageous if the stent is implanted using an implantation device, in such a manner that at first a catheter is inserted into the body vessel to be treated. The catheter is so dimensioned that both the stent as well as a special pusher arrangement, consisting of two pushers, can be inserted into the body vessel. The pusher arrangement consists of an outer and an inner pusher. The diameter of the outer pusher corresponds to the inner diameter of the insertion catheter and has approximately the same outer circumference as the stent in its introduced state, i.e. it corresponds approximately to the overall circumference of the inserted elongated filaments. With the aid of this pusher, the stent is advanced through the catheter until it reaches its preferred site in the body vessel, where it then assumes its preferred state, namely the double-spiral structure of the filaments. A borehole extends axially through the outer pusher, and through the said borehole a second, inner pusher is inserted. This latter pusher is thin but made of a strong material such as Nitinol, and it is

provided at its distal end with means by which it is connectable to the distal end of the stent.

When it is introduced in its elongated state into a body vessel, the stent is advanced in the catheter with the aid of the outer pusher. When the stent emerges from the catheter, i.e. when some loops of the double spiral have already formed in the vessel, the stent is held coaxially in the vessel with the aid of the inner pusher. This prevents the stent from springing backwards or forwards in the body vessel. In this way, it is possible to position the distal end of the stent precisely in the body vessel. The distal end of the stent is still held in place by the thin pusher when the catheter is withdrawn and/or the stent is advanced by the outer pusher. Alternatively, once the catheter has been positioned, the stent can also be drawn into the body vessel by means of the inner pusher, which is connected to the distal tip of the stent. By this means, the stent is axially extended during the implantation procedure, and the friction between the filaments and the wall of the catheter is thereby reduced. The thin pusher is not released from the tip of the stent until the stent has been fully introduced into the body vessel. It is in principle possible to position the stent in the body vessel using just one pusher; however, the combination of both pushers permits especially precise and trouble-free implantation and placement of the stent in the body vessel.

A screw thread is an advantageous means of connecting the inner pusher with the stent, said screw thread being arranged preferably at the distal end of the inner pusher and engaging in appropriate connecting means on the stent, for example a loop formed by the two spirals of the double spiral at the distal end of the stent. Of course, the stent may also have appropriate connecting means provided at its distal end, for example in the form of a threaded borehole matched to the thread on the pusher. Alternatively, mutually corresponding hooks arranged at the tip of the stent and on the pusher may be used. It is also possible to join the stent and the pusher by means of a special soldered joint which can be caused to dissolve in the body by applying an appropriate

electrical current. Such a principle is already used in the case of embolization coils.

In the course of a number of treatments, it has been discovered that the lumen of a body vessel remains open after a certain amount of time, even without the support of a stent. It is thus appropriate to provide devices by means of which the stent can be removed again from the vessel after a certain time. For this reason, the stent is detachably connected to the outer pusher. Again, a screw thread may be used as the means of connection, or a holding element may be arranged at the proximal end of the stent and said holding element can be grasped using an appropriate hook on the pusher. It is thus not necessary to leave the pusher inside the body during the entire dwell time of the stent. After a predetermined time, the stent can be withdrawn from the body vessel through the catheter by the outer pusher.

If the filaments of the stent are made from a material having thermal-memory properties, the stent should be implanted by a catheter filled with a cooling liquid in order to prevent the stent wire from assuming the more voluminous spiral form while it is still in the catheter, thereby impeding the implantation because of the friction between the stent wire and the inner wall of the catheter.

As an alternative to the implantation device of the aforementioned type possessing two pushers, the stent according to the invention may be implanted by a device in which a pusher, which is introduced into the body vessel by means of a catheter, is provided at its distal end with means for supporting the stent inside the catheter.

A fork arranged at the distal end of the pusher is provided as a particularly advantageous means of support; during implantation, the tines of this fork engage over the filaments at their cross-over or connection points, or at the sleeves joining the filaments together, and thus permit particularly reliable

guidance of the stent while it is being implanted in its correct position in the body vessel.

In another advantageous embodiment, a tongs device is provided as the proximal supporting means, and said tongs firmly grasp the filaments, or the sleeves joining the filaments to one another, while the stent is being implanted. However, after - for example - an axial manipulation of the catheter, the tongs are detached again from the stent. In this way, if the stent is wrongly positioned, it can also be withdrawn in the direction of the catheter.

In another advantageous embodiment, the support means on the pusher is hook-shaped and at its distal end the stent possesses a sleeve joining the filaments together, said sleeve possessing a notch which engages positively and can be connected in an axially rigid manner with the hook inside the catheter. This embodiment is also characterized by particularly reliable guidance of the stent during implantation.

Brief Description of the Drawings

The invention is described in the following on the basis of several embodiments schematically illustrated in the attached drawing. In the views, which are not drawn to scale:

Fig.1 shows a top view of a stent having two oppositely oriented spiral filaments, said stent being depicted here in its preferred state;

Fig. 2 shows a view of the stent in the direction indicated by the arrow II in Fig. 1;

Fig. 3 shows a view of the stent in the direction indicated by the arrow III in Fig. 1;

Fig. 4 shows a stent consisting of three spiral-shaped filaments in a view similar to that in Fig. 2;

Fig. 5 shows a stent partially in its elongated implantation form in a catheter and partially in its preferred state in a body vessel;

Fig. 6 shows on an enlarged scale the detail VI from Fig. 5 depicting the cross-over region of two filaments

Fig. 7 shows another stent in the implanted state;

Fig. 8 shows a stent having arcuate filament sections in its preferred state, the said filament sections being joined together by joining means;

Fig. 9 shows a stent in its preferred state having arcuate filament sections;

Fig. 10 shows a lateral view of the stent in Fig. 9;

Fig. 11 shows another embodiment of a stent in its preferred state, in which the filaments possess the alternating form of arcs and spirals respectively;

Fig. 12a shows a sleeve consisting of a material having thermal-memory properties, in the state before two filaments are joined;

Fig. 12b shows the sleeve depicted in Fig. 12a, in its preferred state enclosing two filaments;

Fig. 13 shows a stent provided with a sheath consisting of a fibre structure, in a view similar to that shown in Fig. 1;

Fig. 14 shows the stent depicted in Fig. 13, in a view similar to that in Fig. 2;

Fig. 15 shows various possibilities of configuring the overlapping regions of fibres proceeding from adjacent filaments in the stent according to Fig. 13;

Fig. 16 shows a filament consisting of individual wires twisted together and incorporating a fibre structure in the twists;

Fig. 17 shows a sheathed filament with an incorporated fibre structure;

Fig. 18 shows a partial view of a kissing stent in longitudinal section;

Fig. 19 shows a cross sectional view of the kissing stent seen in Fig. 18, with an internal fibre structure at the distal end;

Fig. 20 shows a cross sectional view of a filament joined to a hook-and-loop tape;

Fig. 21 shows a partial view of a longitudinal section through another kissing stent;

Fig. 22 shows a cross sectional view of the kissing stent from Fig. 21;

Fig. 23 shows another embodiment of a kissing stent;

Fig. 24 shows a cross sectional view of the kissing stent from Fig. 23 along the line XXIV-XXIV in Fig. 23;

Fig. 25 shows a stent provided with a sheath of elastically deformable material in a view similar to that in Fig. 1;

Fig. 26 shows an enlarged view of part of the sheathing of the stent seen in Fig. 25;

Fig. 27 shows another embodiment of a stent having spiral loops spaced at a distance from each other in the longitudinal direction of the stent;

Fig. 28 shows a stent and a device for implanting a stent;

Fig. 29 shows a stent and another embodiment of a device for implanting a stent, seen in lateral view;

Fig. 30 shows a stent and another embodiment of a device for implanting a stent, seen at the proximal end of the stent during implantation;

Fig. 31 shows the distal end of a stent with another embodiment of an implantation device, seen in lateral view; and

Fig. 32 shows a top view of the stent and the implantation device seen in Fig. 30.

Detailed Description of the Preferred Embodiments

The stent 1 shown in Figs. 1 to 3 consists of two filaments 2, 2' which are wound into two oppositely oriented spirals 3, 3'. At the distal end of the stent 1 the two spirals 3, 3' merge into each other via a loop 4 which joins together the two filaments 2, 2' . The filaments 2, 2' are thus parts of a single wire. At the proximal end of the stent 1, the two filaments 2, 2' are joined together by a connecting means, for example a sleeve 5 engaging over the two filaments 2, 2'. However, instead of using sleeves, the ends may also be joined by welding, soldering or glueing. Both the loop 4 at the distal end of the stent 1, and the sleeve 5 at the proximal end, are arranged at the radial outer ends relative to the length of the stent 1. In this way, a uniform lumen is kept open over the entire length of stent 1.

Fig. 4 shows a stent 10 constructed of three spiral-shaped filaments 2, 2', 12. The filaments 2, 2' possess substantially the same pitch and form the double-spiral structure known from Figs. 1 to 3. At least sections of filament 12 possess a different pitch from that of the filaments 2, 2'. In this way, the

filament 12 also supports the vessel in the area of the gaps in the double-spiral structure formed by the filaments 2, 2'.

Fig. 5 shows a stent 1 while it is being implanted in a body vessel 21. The filaments 2, 2' of the stent 1 are advanced through a catheter 22 by a pusher, which is not shown here, in a manner to be described in more detail below. The filaments 2, 2' may optionally consist of thermal-memory wire, such as Nitinol, or an elongated, flexible wire made from highly elastic plastic material may be used. The filaments 2, 2' of the stent 1 emerge at the proximal end of the catheter 22 inside the body vessel 21 to be treated, and because of the aforementioned thermal-memory property, or because of their elasticity, they assume the desired double-spiral shape.

If a thermal-memory wire is used, the catheter 22 should be flushed with a chilled physiological saline solution in order to prevent the filaments 2, 2' from assuming the spiral shape while they are still inside the catheter 22. Otherwise, the frictional force impeding the advance of the filaments 2, 2' in the catheter would be considerably increased by the bulky shape assumed by the filaments 2, 2'. For this purpose, an inlet valve for the physiological saline solution may be provided at the proximal end of the catheter 22 and, in addition, an outlet valve may be provided at the distal end of the catheter 22, said valve allowing the physiological saline solution to be discharged unhindered, but on the other hand preventing the ingress of warm body fluid.

In order to increase the stability of the stent 1 in its preferred state, the filaments 2, 2' are provided with an arrangement of threads 25, at least in the area of the cross-over points 24. In the embodiment depicted, the threads 25 are wound in spiral fashion around both spirals formed by the filaments 2, 2'. In the cross-over zone 24, the thread 25 on one of the filaments 2, 2' is detached from the filaments 2, 2' in such a manner that a space is formed between the thread 25 and the filaments 2, 2', said space being large enough to receive the other filament 2, 2'. When the preferred double-spiral structure of the stent 1 is formed from the elongated implantation structure, the

filaments 2, 2′ forming the spirals are forced to twist in relation to each other. For this reason, the connection of the two filaments 2, 2′ in the cross-over region 24 must be designed in such a manner that the two filaments 2, 2′ can twist relative to each other. Effective radial stability of the stent is achieved by the type of connection shown in Fig. 6, while at the same time the two filaments 2, 2′ can twist relative to each other. Also, the filaments 2, 2′ possess a certain amount of axial mobility relative to each other. This is particularly advantageous when the stent is implanted in greatly curved body vessels.

In the embodiment illustrated in Fig. 7, the individual loops of the spirals 3, 3′ are bent in such a way that, at the cross-over points 24, they run approximately at right angles to each other. Both spirals 3, 3′ are in contact with the inner walls of a body vessel 21. One of the spirals 3, 3′ may have an indentation in which the other spiral 3, 3′ is received, only in the area of the cross-over points 24, as illustrated, for example, in Fig. 25.

In the embodiment depicted in Fig. 8, the spirals 3, 3′ are joined together with each other at their cross-over points by suitable connecting means, such as sleeves 27 engaging both filaments 2, 2′. However, thread connections, of the type illustrated in Fig. 6, may also be used as connecting means.

In the embodiment illustrated in Fig. 9, instead of a double spiral the distal section of the stent 1 possesses a structure consisting of oppositely oriented arcuate sections 29, 29′ running radially at the inner wall of the body vessel 21. Adjacent arcuate sections 29, 29′ of a filament 2, 2′, are therein offset by approximately 180° in relation to each other in a peripheral direction, thus ensuring that the stent 1 has a particularly stable shape. In order to further stabilize the stent, the filaments 2, 2′ are joined together by sleeves 27 in the area where the arcuate sections 29, 29′ are closest to each other. Of course, suitable sleeves 27 may also be arranged in the cross-over region 24 of two filaments 2, 2′ of a stent of the type shown in Figs. 7 or 8, and the filaments may also be joined together with one another in a different way, e.g. by

welding, glueing or soldering, or through a combination of welding, soldering or glueing with sleeves. Depending on the application, the wires can rotate in relation to each other or they are rigidly joined together by the aforementioned connecting means.

Fig. 10 shows, in lateral view, that the filaments 2, 2' of the stent according to Fig. 9 each possess an approximately S-shaped course between two points of maximum proximity between the arcuate sections 29, 29' - in Fig. 10 these are indicated by the sleeves 27 joining the filaments together. In contrast to the stent structure previously known from WO 94/03127, in which filaments run parallel to each other between in each case two connecting sections, the stent structure in the present embodiment possesses a particularly high degree of flexibility. The stent according to Fig. 7, or the stent according to Fig. 8, may also have this configuration, i.e. may be formed from filaments 2, 2' having a substantially S-shaped course - seen in lateral view - between in each case two adjacent cross-over points 24. Because of this S-shaped course of the filaments, the stent possesses an extremely high degree of flexibility and in particular the vessel with the implanted stent is thereby compressible. A pulse wave can pass along such a stent much better than in the case of a stent having filaments oriented perpendicular to the longitudinal axis of the stent.

In the embodiment according to Fig. 11, the filaments 2, 2' of a stent 1 possess an alternating sequence of arcuate sections 29, 29' and spiral loops 30, 30'. On both filaments 2, 2', the sequences are offset such that in the area of the cross-over points 24 of the two filaments 2, 2' a spiral loop 30, 30' in each case intersects with an arcuate section 29, 29'.

Figs. 12a and b illustrate a preferred embodiment of a sleeve 27 connecting in each case two filaments 2, 2'. The sleeve 27 is made of a material having thermal-memory properties and in Fig. 12a it is shown in the state prior to connecting the filaments, i.e. in a substantially rectangular and plane configuration. Once a predetermined thermal-memory transition temperature has been reached, the sleeve 27 assumes a substantially U-shape and encloses

the filaments 2, 2', thereby providing a particularly stable connection that substantially prevents twisting of the filament wires 2, 2' relative to each other. The sleeves 27 may be of different length, depending on the respective requirements. For example, in the areas where the stent body is exposed only to light loading, the number of spiral loops 3, 3' per unit length of the stent may be reduced in a simple manner by providing an appropriately elongated sleeve in the cross-over region to join the two filaments 2, 2'. On the other hand, it is advisable to use short sleeves at the ends of the stent because the stress on the stent is particularly high here and a high spiral density is desirable.

In the embodiment illustrated in Figs. 13 and 14, the filaments 2, 2' of the stent 1 are combined with a fabric or metal structure 45 in such a way that a tubular sheathing of the stent 1 results. Because of its porosity, the sheathing formed by the fabric or metal structure 45 allows diffusion to occur; however, when textile fabric parts are used, the sheathing is very finely porous, whereas when metal fabric is used, the sheathing is very coarsely porous. The decision whether to use a fabric or metal structure depends on the desired rigidity of the stent 1 and on the required diffusion properties.

The fibres or fabric parts proceeding from adjacent spiral loops 46, 47 adjoin each other in an overlapping region 50 between the adjacent spiral loops 46, 47. The manner in which the individual fabric parts and/or fibres adjoin each other may be variously configured, as is apparent from Fig. 15.

Fig. 15 shows partial views of various embodiments a) -d) of the overlapping region 50 between fibres or fabric parts of the fabric structure 45 proceeding from adjacent spiral loops 46, 47, using adjoining fibres 48, 49 as the example. The densest and strongest connection between the fabric parts or fibres is achieved when the fibres 48, 49 proceeding from adjacent spiral loops 46, 47 overlap. This situation is depicted in Fig. 15a and Fig. 15b. While in the embodiment according to Fig. 15a the fibre density of the fabric structure 45 remains constant over the length of the stent, in the case of the embodiment

illustrated in Fig. 15b, zones of greater density and thus greater thickness of the fabric structure 45 result in the area of overlap 50 of the fibres 48 and 49.

Fig. 15c depicts another embodiment in which the fibres do not overlap but merely their ends are in contact with each other, thereby forming a circular transition zone extending over the outer periphery of the stent 1. A stent of this design exhibits lower stiffness and strength compared with the embodiments illustrated in 15a and 15b, but it requires considerably less material in its manufacture and is thus significantly lighter in weight than the aforementioned embodiments. In addition, the catheter used to introduce the stent can have a smaller lumen. Finally, in the embodiment according to Fig. 15d, the fibres 48, 49 again do not overlap, but instead the fibres 48, 49 are designed in such a way that their ends form an undulating transition line 51 in the transition zone 50.

Figs. 16 and 17 illustrate various means of combining a fabric structure with the filaments 2, 2'. According to Fig. 16, filament 2 is provided with fibres 48 extending radially away from the filament 2. The fibres 48 consist mostly of Dacron or Teflon material and, in certain sections or depending on the preferred orientation, they may have different lengths. In Fig. 16 the filament 2 is manufactured from sub-filaments 55, 55' which are twisted together. The sub-filaments 55, 55' also consist of thermal-memory wire or highly elastic plastic material. The Dacron fibres 48 are held between the individual sub-filaments 55, 55' by means of twisting these sub-filaments 55, 55'. This embodiment does not require the use of any adhesives of doubtful or limited durability that are foreign to the body.

In the embodiment illustrated in Fig. 17, a filament 2 is wrapped in a sheath 56. This sheath 56 may also consist of a textile or metal fabric structure. An auxiliary thread or auxiliary wire may also be used and may be attached to the filament 2 by means of a thread 25, for example as shown in Fig. 6. In this embodiment as well, the sheathing 56 is wrapped around the filament 2 in

such a way that it encloses fibres 48 extending radially away from the filament.

The fibres 48 extending away from a filament 2 in the embodiments illustrated in Figs. 16 and 17 also form a sheathing between the individual spiral loops 30, 30' of the stent 1. The interwoven structure formed by the individual fibres 48 may, however, also be specifically used for producing thromboses, for example within a pathological dilatation of a vessel, such as an aneurysm. In accordance with another embodiment, the fibres 48 may also specifically project into the interior of the stent 1 in order to accelerate desired sealing of the vessel.

Figs. 18 and 19 illustrate a stent for a special method of treating vascular disorders in the area of bifurcations of vessels. For this purpose, the so-called kissing stent method is successfully used. In this method, a main stent 1 having a larger diameter is implanted in the bifurcating vessel 60 and then, at the distal end, a further auxiliary stent 61, 61' is inserted through each of the branching vessels into the first implanted stent 1. In the case of a pathological Aorta abdominalis in which an aneurysm has developed, one auxiliary stent 61, 61' is inserted through each of the Arteriae femorales into the distal lumen of the already implanted main stent 1. Up until now this has been problematical because in the area of the bifurcation of the two distally inserted auxiliary stents 61, 61' leakage occurred, due to the fact that the subsequently distally inserted auxiliary stents 61, 61' did not fill the entire lumen of the originally implanted main stent 1. When the fibres 48 are arranged in certain sections to project inwards at the distal end of the main stent 1, as shown in Fig. 19, the leakage described can be effectively eliminated because accelerated formation of thrombi takes place in the leakage zones. However, the fibres 48 may also be arranged projecting radially outwards on the auxiliary stents 61, 61'. Depending on the density and radial extent of the fibres 48, it is in this case under certain circumstances possible to do without the main stent 1 entirely. Effective formation of thrombi then takes place directly between the wall of the body vessel 60 and the auxiliary stents 61, 61'. Of course, instead of the

fibres 48, it is also possible in this case to use another sealing layer, for example a fabric structure. The two auxiliary stents 61, 61' may also consist of a stent 35 formed from a double-spiral structure, and in the area where they are inserted into the main stent, they may possess a "figure-of-eight" cross section. This is shown in Fig. 19.

According to Fig. 20, the fabric or metal structure 45 connected to the filament 2 may be joined to a hook-and-loop tape 63. In the area of the overlaps of the fabric or metal structures 45 proceeding from adjacent spirals, hook-and-loop connections 64 are formed. This improves the transverse stiffness of the stent 1. In addition, the fabric structure 45 may taper outwards with increasing distance from the filament 2 so that, in contrast to the drawing (not to scale) in Fig. 20, a uniform outer contour of the stent 1 is obtained. The rectangular cross section of the stent filaments depicted in Fig. 20 permits an especially firm connection of the hook-and-loop fastener with the filament. In general, a rectangular filament cross section guarantees a more stable attachment of the sheaths and/or fibre material to the stent filaments. As an alternative to the rectangular filament cross section shown in Fig. 20, it is also possible, however, to use filaments having a "D"-shaped cross section. In order to achieve a particularly high degree of tightness of the hook-and-loop connections 64, a balloon catheter should be introduced into the stent after it has been implanted and said catheter should then be briefly inflated in the area of the hook-and-loop connections 64, thus pressing the hook-and-loop tapes 63 against each other.

In addition to the embodiments illustrated in Figs. 18 and 19, a further embodiment of the invention for implementing the kissing-stent method is shown in Figs. 21 and 22. Fig. 21 shows a longitudinal section through an infrarenal aortic aneurysm 62 extending into the bifurcation. Also in this embodiment, two auxiliary stents 61, 61' are provided in the area of the bifurcation of the vessel and follow the branching of the vessel. Instead of the main stent 1 shown in Fig. 18, only the sealing stents 67, 68, 69, which are short in length, are provided in the embodiment illustrated in Figs. 21 and 22.

The cross section in the area of the neck of the aneurysm, which is illustrated in Fig. 22, shows a view of the sealing stent 67 on an enlarged scale compared with Fig. 21. The fibres 48 extending away from the sealing stent 67 project on the one hand radially inwards into the lumen of the vessel and are joined with the auxiliary stents 61, 61', and on the other hand they project radially outwards beyond the outer periphery of the sealing stent 67 and conform to the wall of the body vessel 60 in the area ahead of the aneurysm. This prevents leakage between the two auxiliary stents 61, 61' themselves, as well as between the stents and the wall of the aorta in the area of the aneurysm 65. The function of the sealing stents 68, 69 is analogous to the function of the sealing stent 67. In an advantageous embodiment, the inserted auxiliary stents 61, 61' may also have an oval or D-shaped cross section in order to achieve better filling of the aortic lumen and thus to optimize the sealing effect. In this way, the danger of the aorta rupturing at the aneurysm is effectively prevented.

Another possibility of constructing a kissing stent with the aid of double-spiral stents is illustrated in Figs. 23 and 24. In Fig. 23, the kissing stent is again shown in its implanted state in a body vessel 60, in the area of an aneurysm 65. In this kissing stent, the main stent 1 possesses in its distal section one lumen, whereas in its proximal section it possesses two lumina into which are inserted during implantation the auxiliary stents 61, 61', only sections of which are indicated in Fig. 23. In this proximal section, the two filaments of the main stent 1 are formed in such a manner that, as shown in Fig. 24, in cross section the stent 1 possesses a "figure-of-eight" shape. In this way, a very reliable and stable connection is formed between the main stent 1 and the auxiliary stents 61, 61'. As an alternative to the "figure-of-eight" structure, the proximal section of the stent 1 may also have the form of two oppositely oriented, individual spirals adjacent to and at least almost in contact with each other, at certain points. However, in this case, in order to achieve a degree of stability equivalent to that of the embodiment illustrated in Fig. 23, at their points of contact the oppositely oriented spirals must be joined together, for example by means of sleeves 27 or the threads 25 shown in Fig. 6.

As shown in Fig. 24, also with such kissing stents, it is possible to achieve accelerated thrombus formation by means of using fibres 48 and/or fabric structures projecting radially from the filaments of the main stent 1 and/or the auxiliary stents 61, 61', in the direction of the wall of the body vessel 60. In order to make better use of the lumen of the body vessel 60, the two lumina of the proximal section of the stent 1 may also each possess an oval cross section instead of the circular cross section depicted in Fig. 24.

In Fig. 25, instead of a fibre or fabric structure connected to the filaments 2, 2', the stent 1 possesses a membrane-like sheath 57 which encloses the stent 1 radially on the outside and which is joined by stitches 54 with the filaments 2, 2'. The stitches 54 should preferably be fastened at the ends of the stent 1, but they may also be arranged in other areas of the stent body.

The filaments 2, 2' joined by means of a sleeve 5 at the proximal end of the stent 1 form oppositely oriented spirals , whose individual loops 46, 47 in Fig. 25 possess different pitches over the length of the stent 1. The sheathing 57 consists of a woven textile , but may also consist of a biocompatible, highly elastic material, preferably plastic, latex or silicone. Therefore, on the one hand, the sheath 57 clings tightly to the spiral loops 46, 47 of the filaments 2, 2' so that, in its preferred state, the stent is implanted in the body vessel in an almost radially fixed position; on the other hand, in the area between adjacent spiral loops 46, 47, the sheath 57 possesses a lumen that corresponds at least approximately to the lumen of the spiral loops 46, 47. Without impairing the stability, the sheath 57 also encloses the indentation in one of the two filament wires 2, 2' in the area of the cross-over points 24 in the embodiment shown in Fig. 25.

Fig. 26 is an enlarged view of a section of the sheath 57 of the stent 1 from Fig. 25 in its preferred implantation state. In this state, the diamond-shaped meshes 58 are distributed over the outer periphery of the stent body formed by the filaments 2. Depending on the degree of expansion of the stent in its implanted position, the angle enclosed by the sides of the diamond-shaped

meshes 58 may vary in size, up to the point where the meshes 58 are approximately rectangular in shape. On the other hand, in the extended state of the stent, the threads forming the meshes 58 of the sheath 57 run approximately parallel to one another. In order to prevent the textile threads of the sheath 57 from penetrating into the intermediate area between the spiral loops 3 of the filaments in the implanted state, the sheath 57 is additionally provided with reinforcing threads 59, preferably made of metal, which in the embodiment according to Fig. 26 are worked into the sheath 57, also in a mesh pattern, and in the implanted state of the stent 1 run approximately at right angles to each other.

Fig. 27 shows another embodiment of a stent 1 according to the invention in which the filaments 2, 2′ are arranged parallel to each other over most of the length of the stent 1, but widen at predetermined intervals into oppositely oriented spiral loops 66, 66′. When the stent 1 is implanted by means of a catheter 22, the spiral loops 66, 66′ are bent over and lie close against the parallel sections of the filaments 2, 2′. Thus, the axial spacings of the spiral loops 66, 66′ on the stent 1 are so dimensioned that in the extended state of the stent axially adjacent spiral loops 66, 66′ are not in contact with each other, in order to keep the internal diameter of the catheter 22 needed for the implantation process as small as possible. Like the stent shown in Fig. 25 , the stent shown in Fig. 27 is also provided with a sheath 57 consisting preferably of a knitted textile structure. As an alternative to the embodiment shown in Fig. 27, the oppositely oriented spiral loops 66 may also be arranged on one side of the main wire.

Finally, Fig. 28 depicts an advantageous embodiment of an implantation device 70, whereby the stent 1 is introduced as an elongated double filament via a catheter 22 into the body vessel 21, where it assumes its preferred double-spiral structure. Two pushers 71, 72 are used to move the stent into its predetermined position. The outer pusher 71 is used to push the stent filaments 2, 2′, supported against its front end 74, through the catheter 22 to a preferred position in the body vessel. 21. Through the outer pusher 71 there

extends a concentric lumen through which the inner pusher 72 is guided. The inner pusher 72 consists of a thin, but rigid wire possessing a threaded section 73 at its distal end, and by means of said threaded section it is joined to the distal end of the stent 1. A flexible guide wire 75 is arranged at the distal end of the threaded section 73 of the inner pusher 72, the tip of said wire being bent over in order to avoid injuring the vessel when the inner pusher is introduced into the latter.

When introducing the stent 1 into the vessel 21, at first both pushers 71, 72 are advanced in the catheter 22, with the stent 1 in the extended state. As soon as a first section of the stent 1 has assumed its preferred double-spiral structure in the body vessel, the stent is held coaxially to the wall of the vessel 21 by means of the inner pusher 72. This prevents the stent 1 from springing backwards or forwards in the body vessel 21. The threaded section 73 of the inner pusher 72 is firmly but detachably connected to the stent 1 at the end loop 4 which joins together the two filaments 2, 2' of the stent 1. While the catheter 22 is retracted, and at the same time the stent is advanced by the outer pusher 71, the distal end of the stent is held by the inner pusher 72. When the stent 1 has been completely inserted into the body vessel 21, the inner pusher 72 is detached from the end loop 4 of the stent 1. Of course, a threaded connection could also be provided at the tip of the stent in order to achieve a more reliable attachment of the inner pusher 72 to the stent 1.

It is also conceivable for the outer pusher 71 to be detachably connected at its front end 74 with the stent 1, e.g. by means of a threaded connection. Such an embodiment allows an implanted stent to be removed from a body vessel 21 again after it has been implanted for a certain length of time. In another alternative embodiment of the implantation device 70, provision is made that, instead of the pushers 71, 72 being arranged coaxially relative to each other, these are arranged alongside each other in the catheter, such that a first pusher corresponding to the inner pusher 72 projects a predetermined length beyond the distal end of the other pusher.

The implantation device 77 illustrated in Fig. 29 possesses a catheter 22 and a pusher 72 mounted in an axially movable manner therein, said pusher being provided at its distal end with a bent guide wire 75, like the pusher 72 of the implantation device in Fig. 26. At the front section of the pusher 72 adjoining the guide wire 75 there is arranged a fork-shaped widening 78 which engages around the loop terminating the filaments 2, 2′ at the distal end of the stent 1 to be implanted, or which engages around the sleeves 27 that join together the filaments 2, 2′.

Once the catheter 22 has been correctly positioned in the body vessel 21 - not depicted in Fig. 29 - the stent 1 is advanced into the body vessel by means of the pusher 72 acting at a loop 4 terminating the filaments 2, 2′ at the distal end of the stent. After the distal end of the stent has been correctly positioned, the pusher 72 is retracted into the catheter 22 to a point behind the following sleeve 27, which joins together the filaments 2, 2′. Then the pusher 72 is advanced once more, and its fork-shaped widening 78 engages over the following sleeve 27, with the result that the parts of the stent located in the catheter are advanced out of the catheter 22 at this sleeve 27 by means of the pusher 72. By successively actuating the pusher 72 at the sleeves 27 joining the filaments 2, 2′ of the stent 1, it is possible to achieve very reliable and positionally correct placement of the stent 1 in the body vessel.

While the implantation device 77 illustrated in Fig. 29 acts on the distal end of the stent, with the implantation device 80 shown in partial view in Fig. 30, a stent 1 may be guided at its proximal end.

The implantation device 80 also possesses a catheter 22 and a pusher mounted in an axially movable manner therein. A hook element 83 is arranged at the distal end of the pusher. At the same time, the filaments 2, 2′ of the stent 1 to be implanted are joined together at its proximal end by means of an end sleeve 81, which in turn is provided with a notch 82 running transverse to the axial extent of the stent. Said notch may be connected in form-fitting engagement with the hook element 83 of the pusher 72.

During implantation, the distal end of the stent is advanced out of the catheter 22 by means of the pusher 72.

Until the stent 1 has been finally and positionally correctly placed, its proximal end remains in the catheter 22 and is thus connected in an axially rigid manner with the hook element 83 of the pusher 72. In this situation, it is possible at any time to fully retract the stent 1 into the catheter 22.

Detaching the stent 1 from the pusher 72 is simply accomplished by advancing also the proximal end of the stent 1 out of the catheter 22 once the stent 1 has been correctly positioned in the body vessel 21. The stent 1 and the pusher 72 are then freely movable relative to each other perpendicular to the axial extent of the catheter 22 and the end sleeve 81 is thus detachable from the hook element 83.

Another implantation device 85, which is provided to place the distal end of the stent precisely in a body vessel, is illustrated in Figs. 31 and 32. The implantation device 85 is again provided with a catheter and a pusher 72 which is mounted in an axially movable manner therein. The pusher possesses a tongs-shaped front section 86, whose tongs elements 87, 87', engage the distal end of a stent 1 to be implanted, for example at a loop 4 terminating the distal end of the stent 1, or at a sleeve 5, 27 joining the filaments 2, 2' of the stent 1 at the distal end of the latter. In contrast to the implantation device 77 shown in Fig. 29, it is thus possible, with the implantation device 85 shown in Fig. 31, to move the stent 1 backwards and forwards with the aid of the pusher 72, thereby allowing any wrong positioning of the distal end of the stent 1 in the body vessel 21 to be corrected.

The stent 1 is detached from the pusher 72 by first retracting the catheter 22 in the body vessel 21 until at least part of the spiral loops of the stent 1 unfold into their preferred implanted position, as indicated in Fig. 32.

By advancing the catheter 22 again, the latter strikes against the stent 1 in an axial direction with a force - indicated by arrows in Fig. 32 - that is transmitted by the filaments 2, 2' at the distal end and causes the tongs elements 87, 87' to move apart, thus releasing the loop 4.

CLAIMS

1. A stent for treatment of pathological body vessels, which can be implanted permanently and adopts an intended state only at the implantation location during the implantation, and comprises several filaments, wherein the filaments in the intended state of the stent are fixedly connected together at at least one connecting point lying in the region of an outer circumference of the stent, wherein at least two of the filaments in the intended state are, over at least a part of the length of the stent, present in the form of helices of mutually opposite sense to form oppositely oriented spirals, and these filaments of the helices of mutually opposite sense consist of a single filament wire, which at a first of the at least one connecting point of the two helices has a loop for providing a helix of opposite sense, said stent for implantation in the form of at least two longitudinally extended filaments into a body vessel by means of an implantation device and the first of the at least one connecting point of the two helices is respectively arranged at one of the front ends of the stent.

2. The stent according to claim 1, wherein the filaments are made of a material having one of superelastic properties and thermal-memory properties.

3. The stent according to claim 1 or 2, wherein the filaments of the oppositely oriented spirals are cut in one piece from a tubular work piece.

4. The stent according to claim 1 or 2, wherein the two filaments forming the oppositely oriented spirals are glued, soldered or welded together at the connecting point.

5. The stent according to claim 1 or 2, wherein the two filaments forming the oppositely oriented spirals are joined together at the connecting point by means of a sleeve engaging around the two filaments.

6. The stent according to any one of claims 1 to 5, wherein the oppositely oriented spirals are connected to each other at least partially at cross-over points therebetween.

7. The stent according to claim 6, wherein the connection between the oppositely oriented spirals at the cross-over points is formed by loops of threads arranged on at least one of the filaments, such that the filaments are movable, to a limited extent, relative to each other.

8. The stent according to any one of claims 1 to 7, wherein at least three filaments of approximately equal length and having a spiral shape, the third or subsequent filaments possessing at least partially different pitch from the two filaments forming the oppositely oriented spirals.

9. The stent according to any one of claims 1 to 8, wherein the filaments possess the same direction of rotation over at least part of the total length of the stent.

10. The stent according to any one of claims 1 to 9, wherein at least one filament possesses an arcuate section extending along the outer periphery of the stent.

11. The stent according to claim 10, wherein in each case two filaments possess similar, oppositely oriented arcuate sections at least over part of the length of the stent.

12. The stent according to claim 11, wherein at the region where they are closest together, the arcuate sections are firmly connected together, by means of a sleeve joining the filaments, welding, soldering, gluing, or said sections are joined together in such a manner that limited movement of the filaments relative to each other is maintained.

13. The stent according to claim 11, wherein two of the filaments in each case possess an alternating structure in which at least one arcuate section is

followed by at least one complete spiral loop, and the filaments are offset in relation each other, such that in each case one spiral loop on the one filament intersects an arcuate section on the other filament.

14. The stent according to any one of claims 1 to 13, wherein at least sections of the stent possess an oval or "D"-shaped lumen.

15. The stent according to claim 13, wherein the filaments form a double stent consisting of at least two auxiliary stents extending over at least part of the length of the stent.

16. The stent according to claim 15, wherein the auxiliary stents of the double stent are joined to each other at the spiral loops of their filaments.

17. The stent according to claim 16, wherein the stent is shaped at least at its distal end in such a manner that the lumen of the stent possesses the approximate shape of a figure eight.

18. The stent according to any one of claims 1 to 17, wherein it further comprises an elastically deformable membrane sheath.

19. The stent according to claim 18, wherein the membrane sheath consists of a textile fabric.

20. The stent according to claim 19, wherein reinforcing threads are worked into the fabric structure of the textile membrane sheath.

21. The stent according to any one of the claims 1 to 20, wherein at least one of the filaments is provided at least partially with a fabric structure projecting beyond the outer periphery of this filament, or with fibres projecting radially from the filament.

22. The stent according to claim 21, wherein the fabric structures and/or fibres proceeding from the individual, adjacent spirals or arcuate sections formed by the filaments are at least partially in contact with each other at their free ends.

23. The stent according to claim 21 or 22, wherein at least one filament is sheathed and/or wrapped, thereby including projecting fabric structures or radially projecting fibres.

24. The stent according to claim 23, wherein several subfilaments are twisted together with one another to form a single filament, thereby including projecting fabric structures or radially projecting fibres.

25. The stent according to any one of claims 21 to 24, wherein the fabric structures and/or fibres extending radially from the filament are of different length in certain sections or depending on the preferred radial orientation.

26. The stent according to claim 25, wherein the fabric structures or the fibres between the individual, adjacent spiral loops or arcuate sections formed by the filaments are at least approximately in contact with each other along an undulating borderline.

27. The stent according to any one of claims 21 to 26, wherein the fabric structures or the fibres between the individual, adjacent spiral loops or arcuate sections formed by the filaments at least partially overlap.

28. The stent according to any one of claims 21 to 27, wherein the fabric structure consists at least partially of a textile structure.

29. The stent according to any one of claims 21 to 27, wherein the fabric structure is produced at least partially from metal fabric.

30. The stent according to claim 28 or 29, wherein at least sections of the fabric structure are fringe-like cut.

31. The stent according to any one of claims 28 to 30, wherein the fabric structure is provided with bonding means.

32. The stent according to any one of claims 28 to 30, wherein the cross section of the fabric structure is formed in such a manner that it tapers with increasing distance from the filament.

33. The stent according to any one of claims 1 to 32, wherein a sealing stent possesses fabric structures or fibres that project radially into the lumen of the stent or radially beyond the outer periphery of the stent.

34. The stent according to any one of claims 1 to 33, wherein at least one of the filaments is provided with markings that permit external observation of the stent using diagnostic means.

35. The stent according to any one of the claims 1 to 34, wherein at predetermined intervals along the length of the stent the filaments form oppositely coiled loops defining the outer radius of the stent.

36. The stent according to claim 2 wherein the filaments are made from Nitinol.

37. The stent according to claim 3 wherein the filaments are cut using a laser.

38. The stent according to claim 12 wherein the sections are joined together by loops of threads arranged on at least one of the filaments.

39. The stent according to claim 20 wherein the reinforcing threads are made of metal.

40. The stent according to claim 34 wherein the diagnostic means is an X-ray.

41. The stent according to claim 31 wherein the bonding means is a hook-and-loop fastener, to join the overlapping fabric structures

FIG. 1

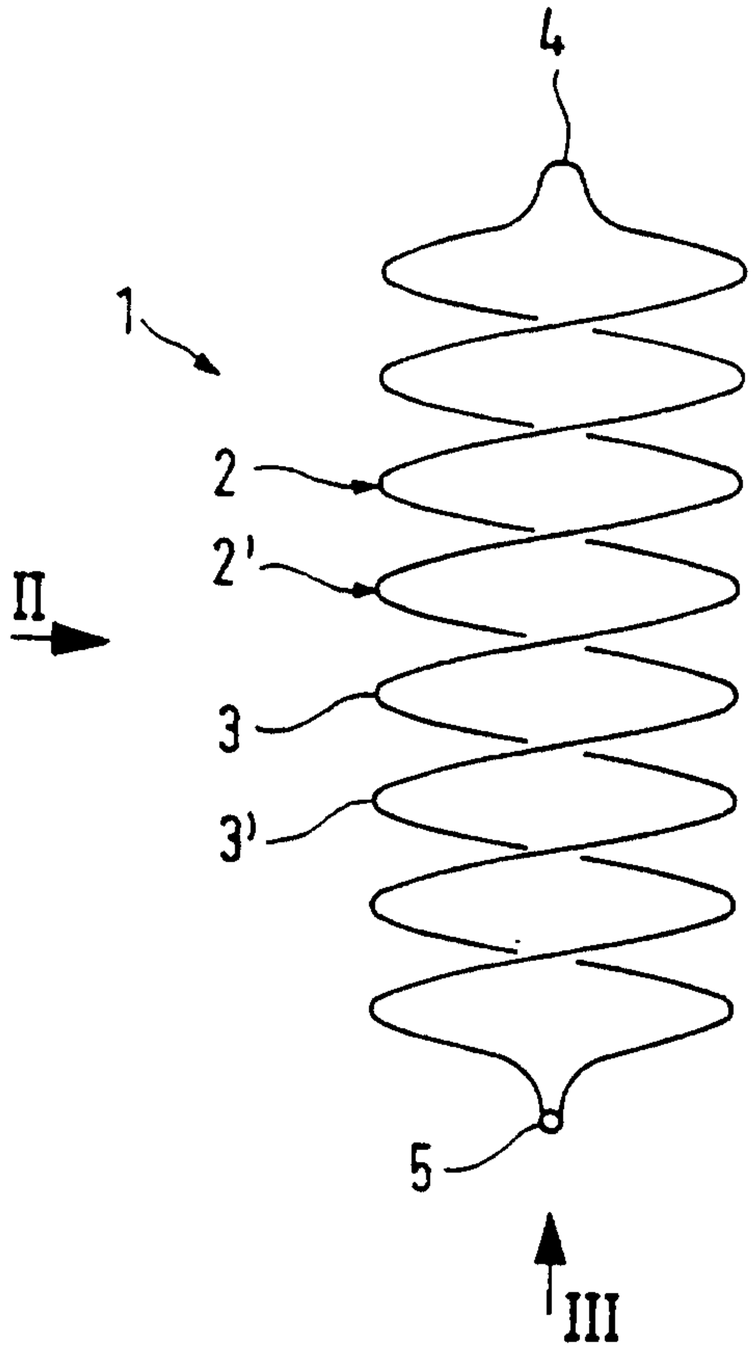
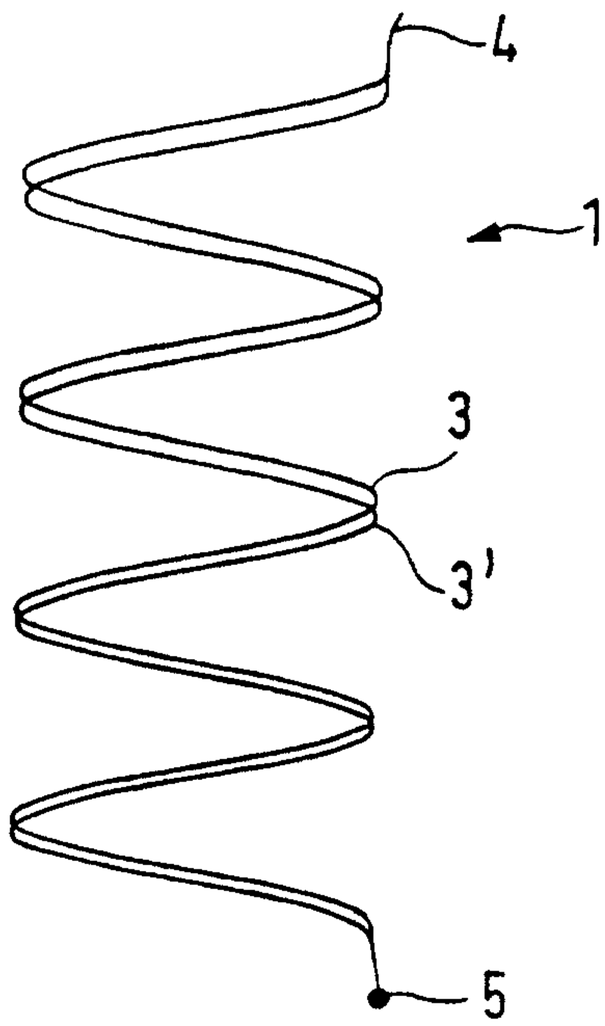


FIG. 2



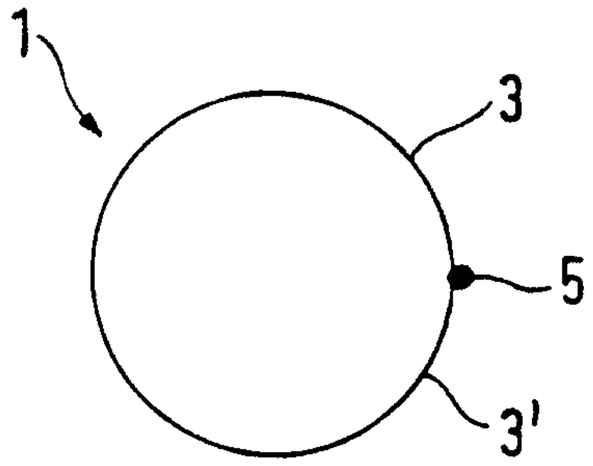


FIG. 3

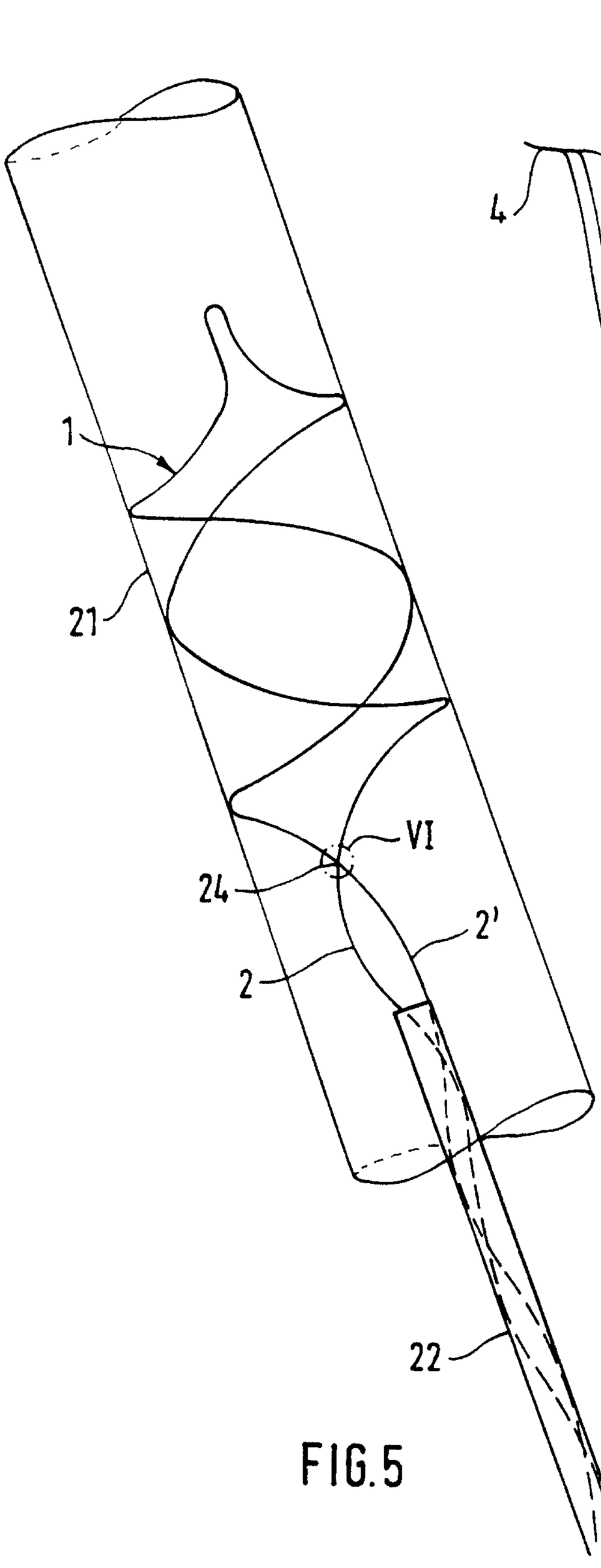


FIG.5

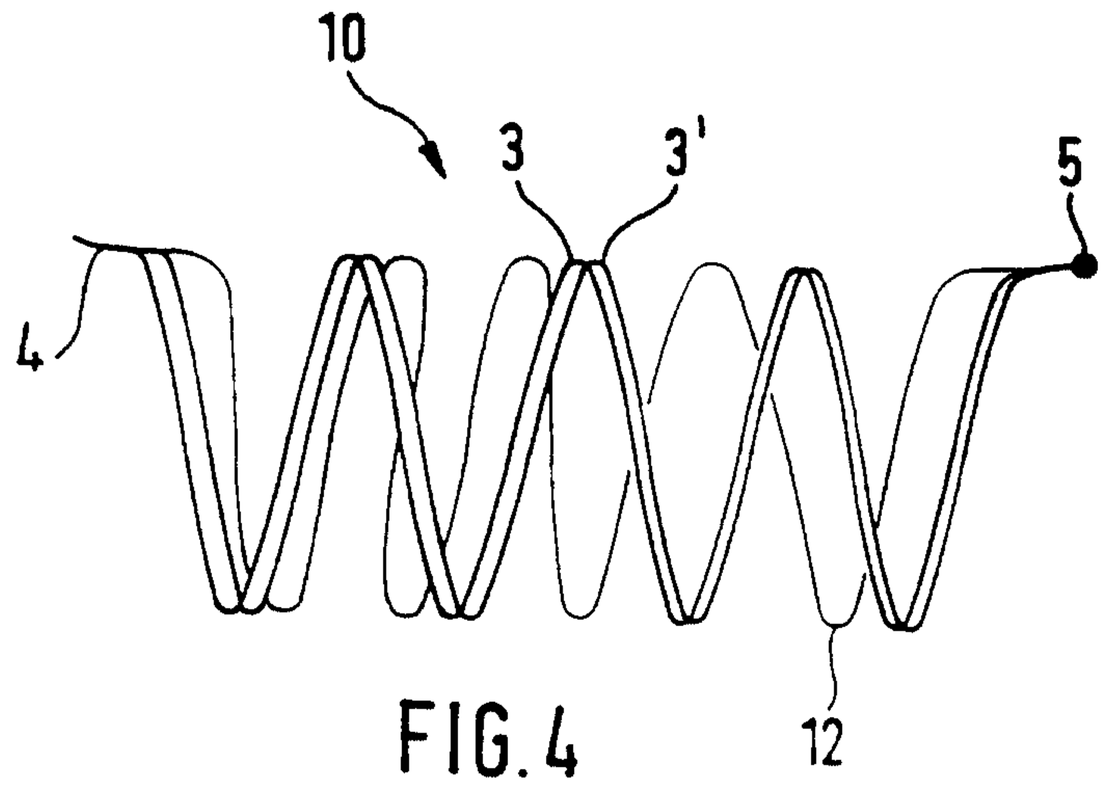


FIG.4

FIG.6

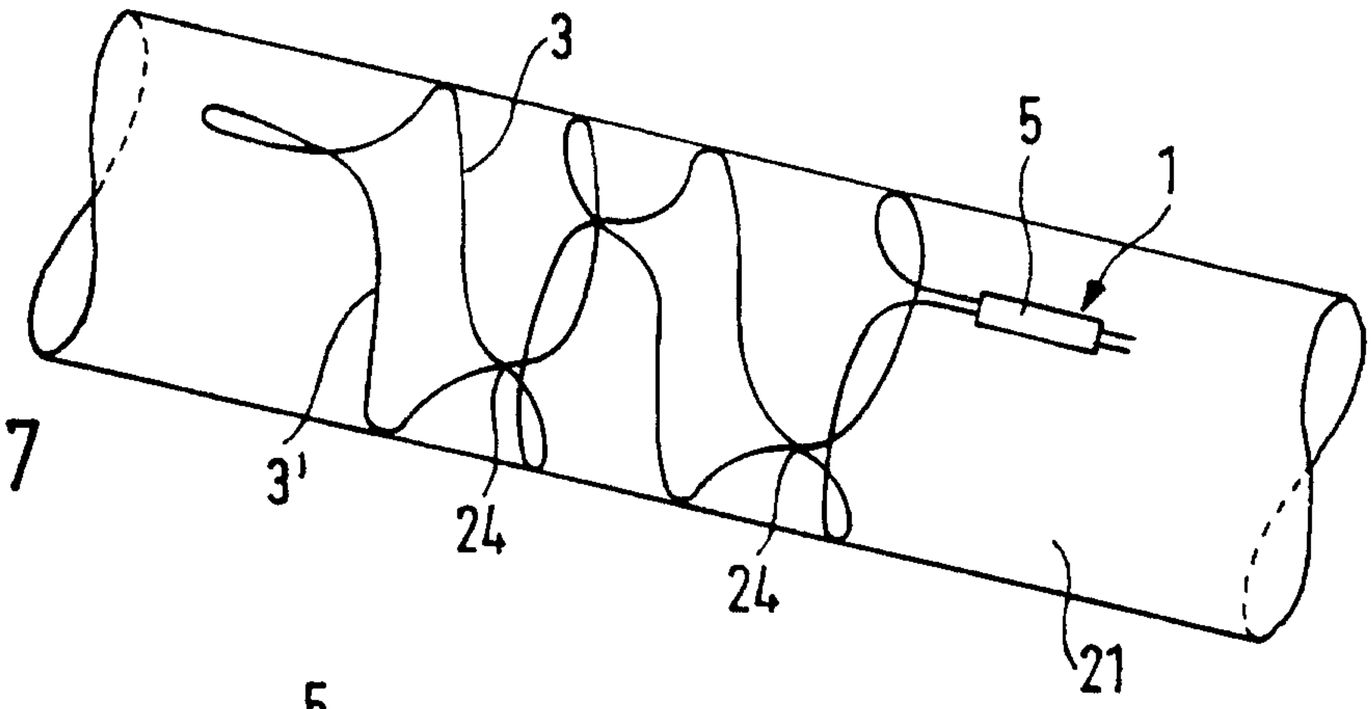


FIG.7

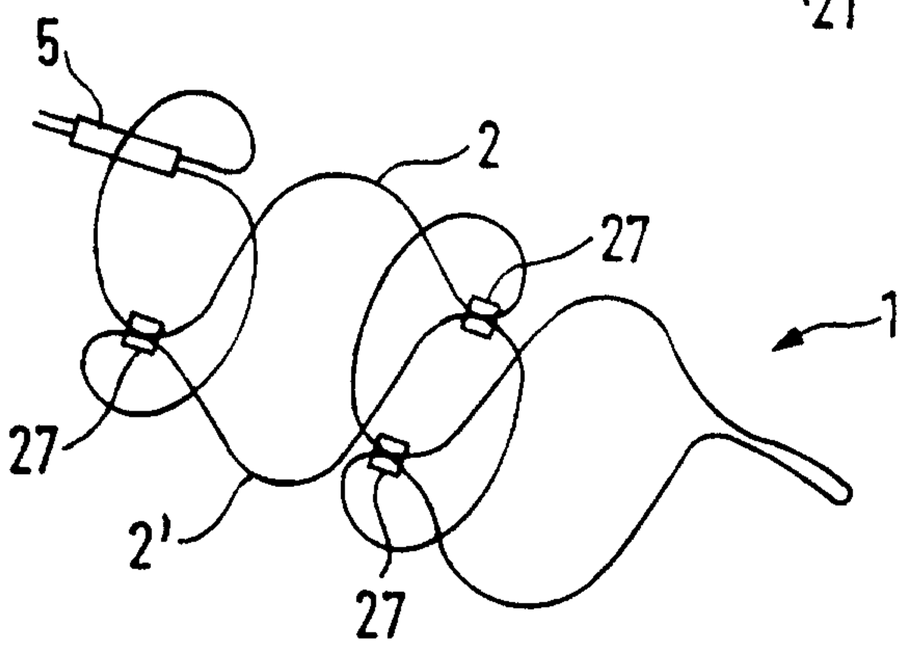


FIG.8

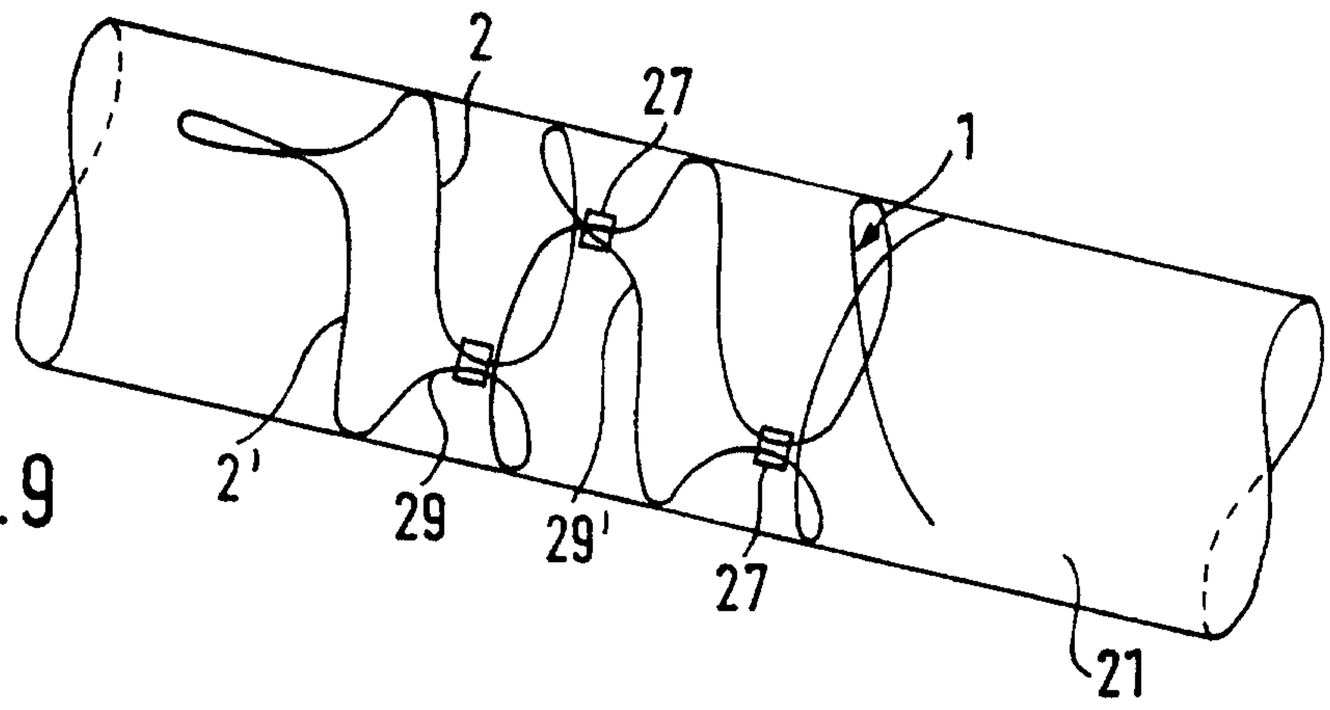


FIG.9

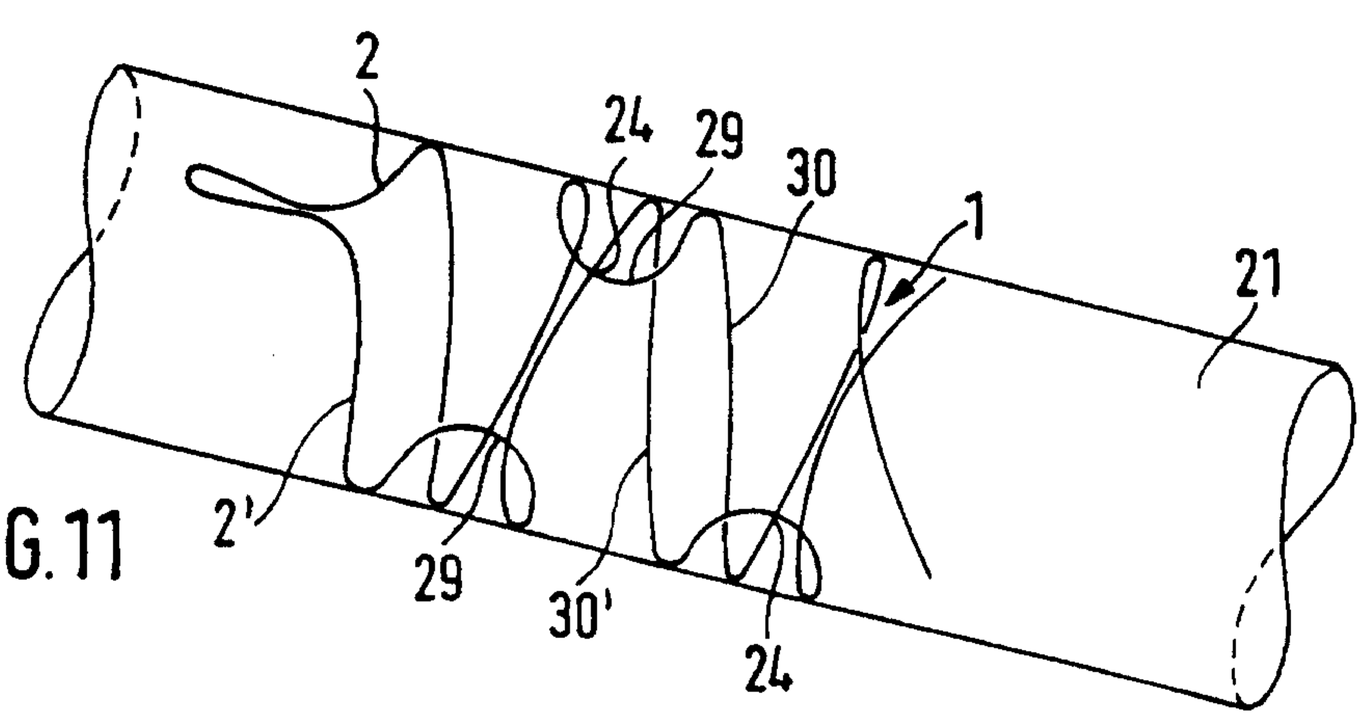


FIG.11

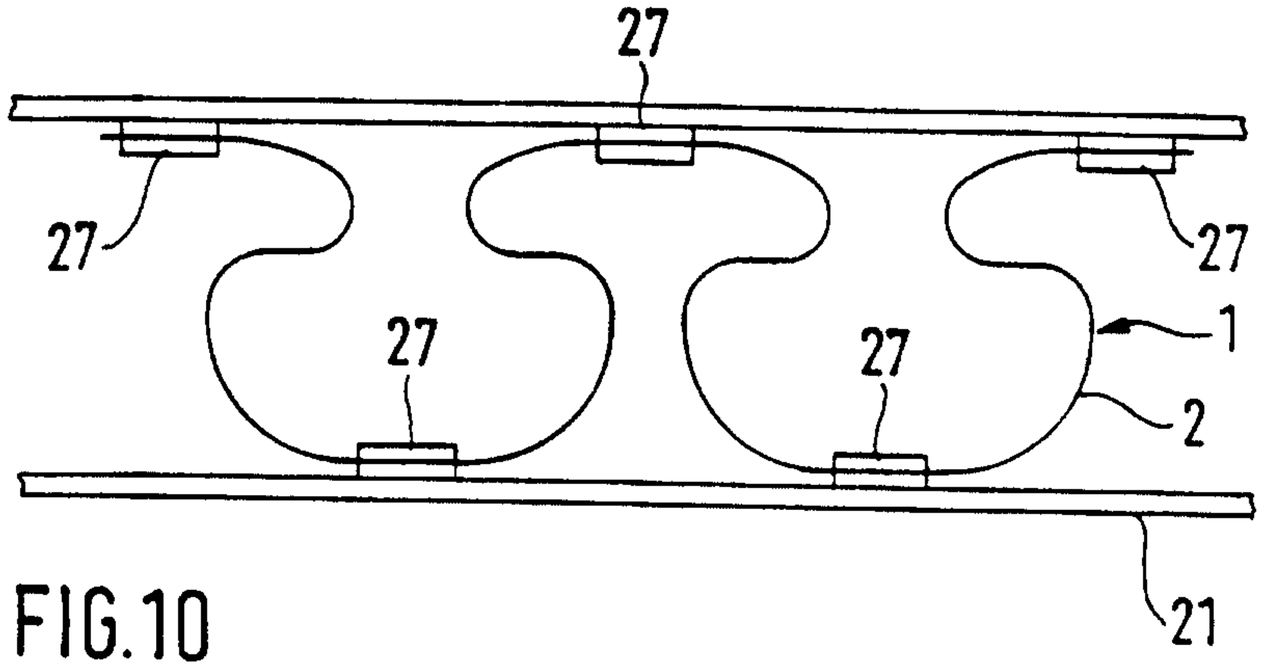


FIG.10

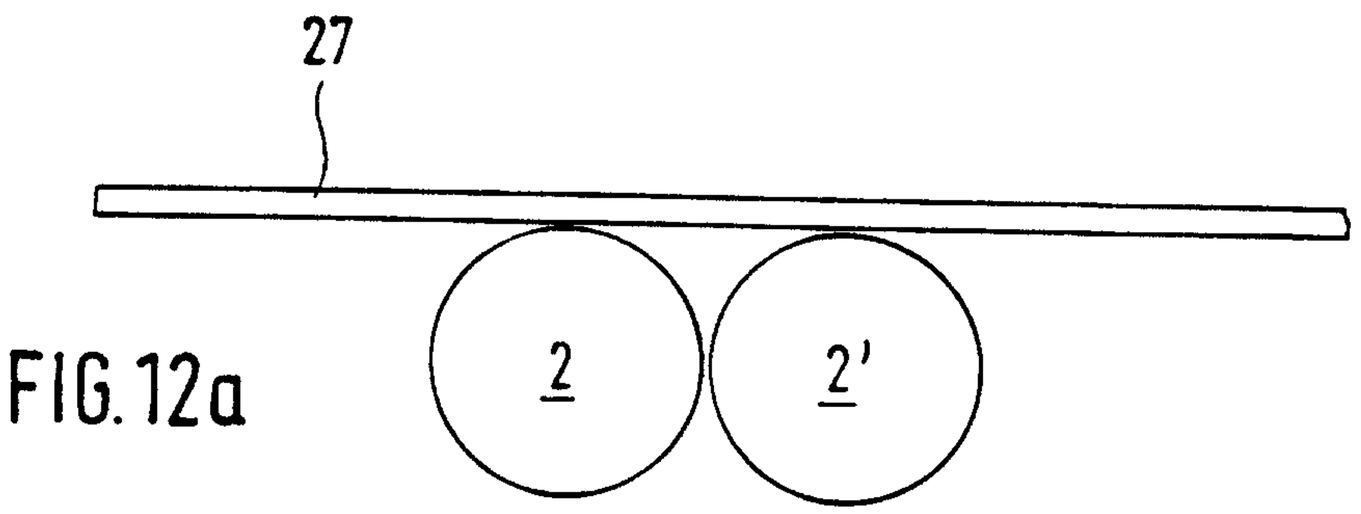


FIG.12a

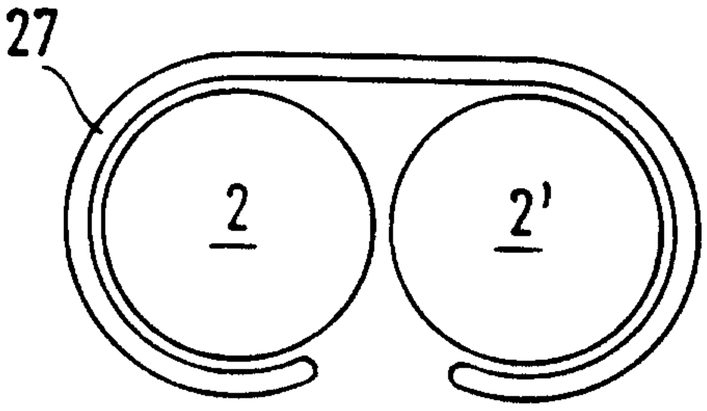


FIG.12b

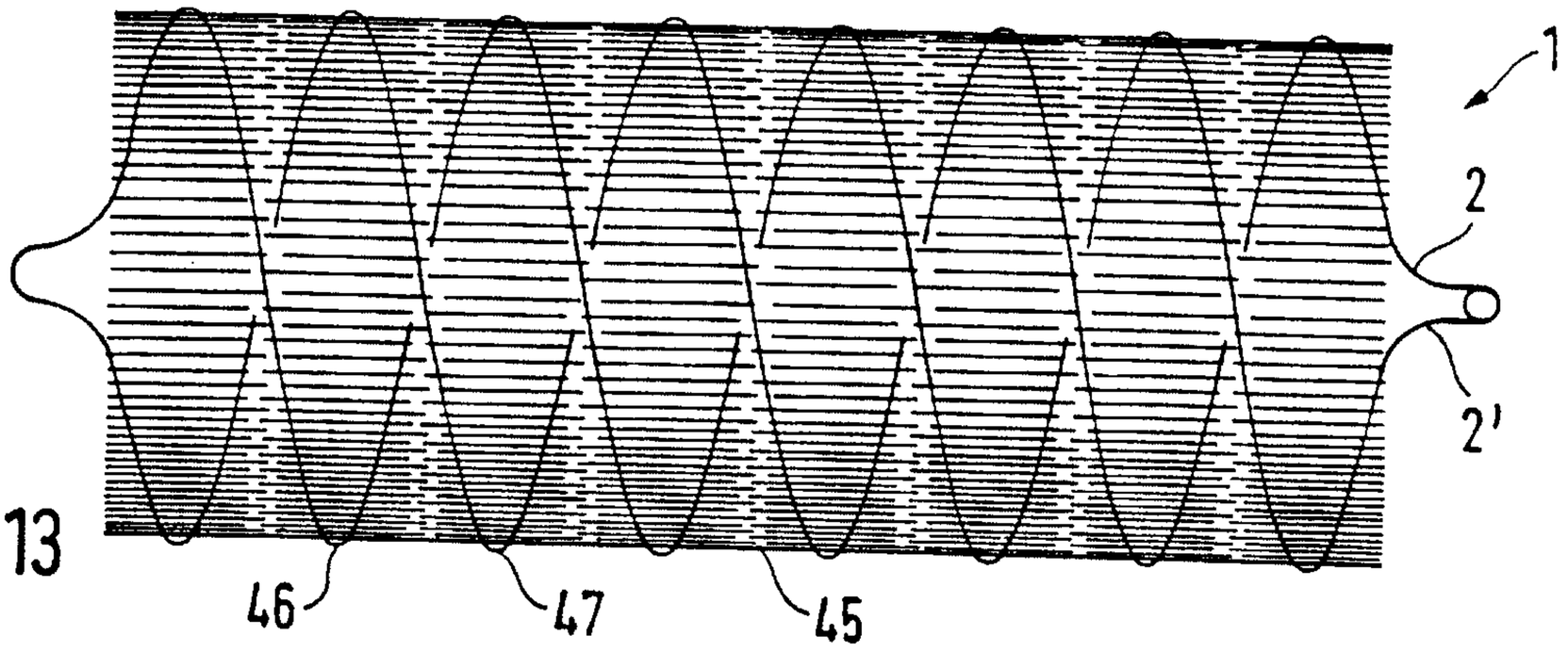


FIG. 13

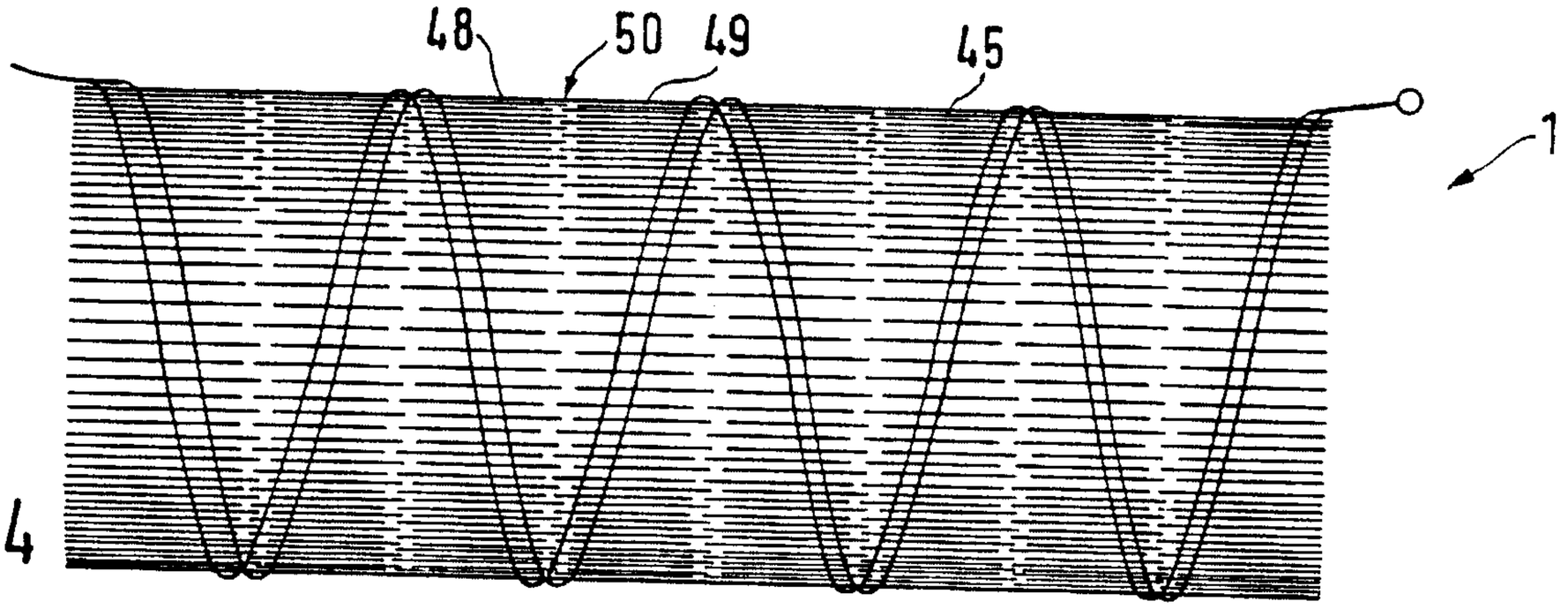


FIG. 14

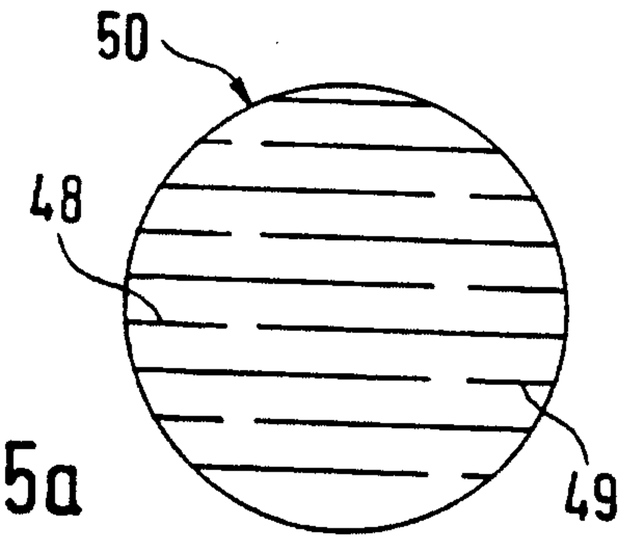


FIG. 15a

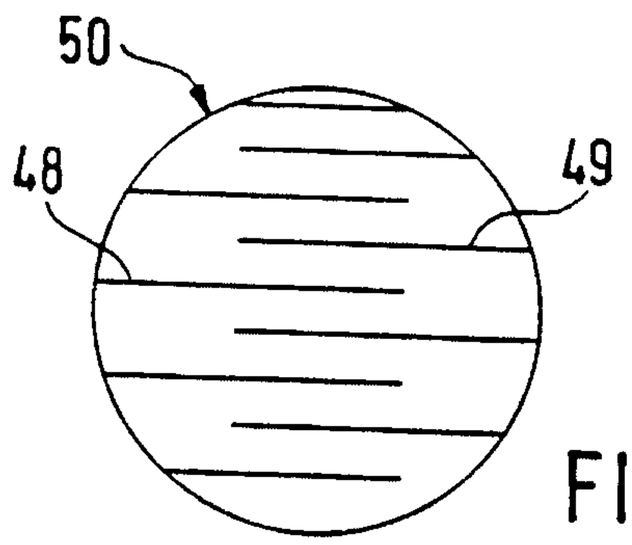


FIG. 15b

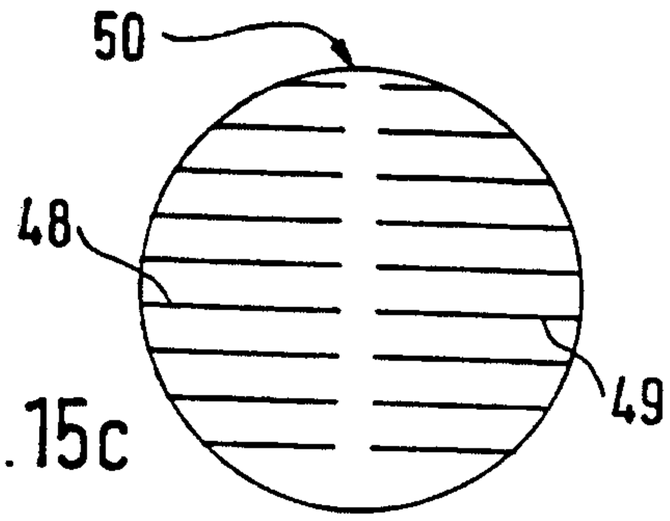


FIG. 15c

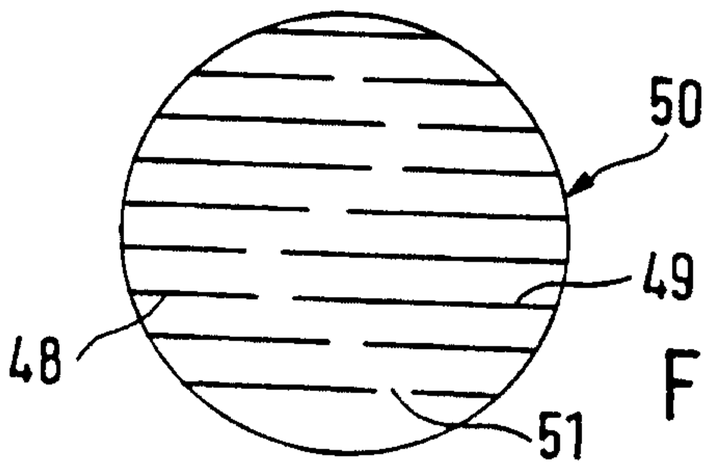


FIG. 15d

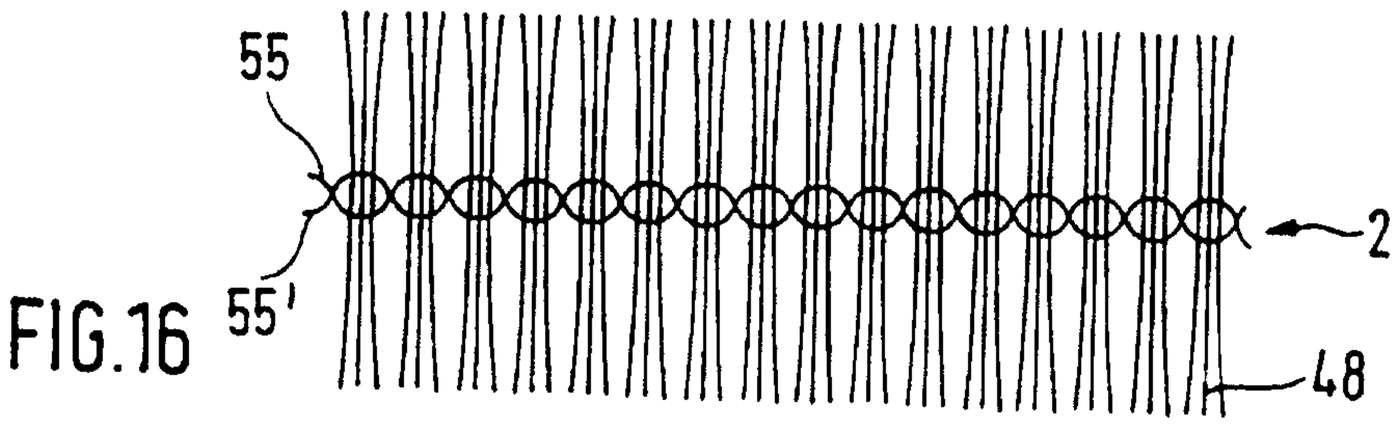


FIG.16

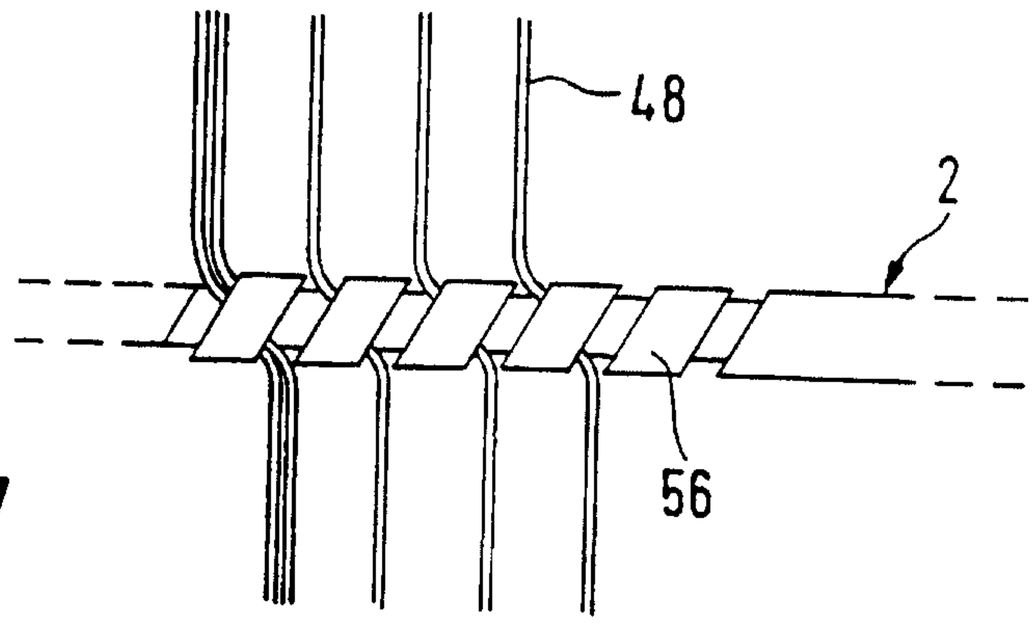


FIG.17

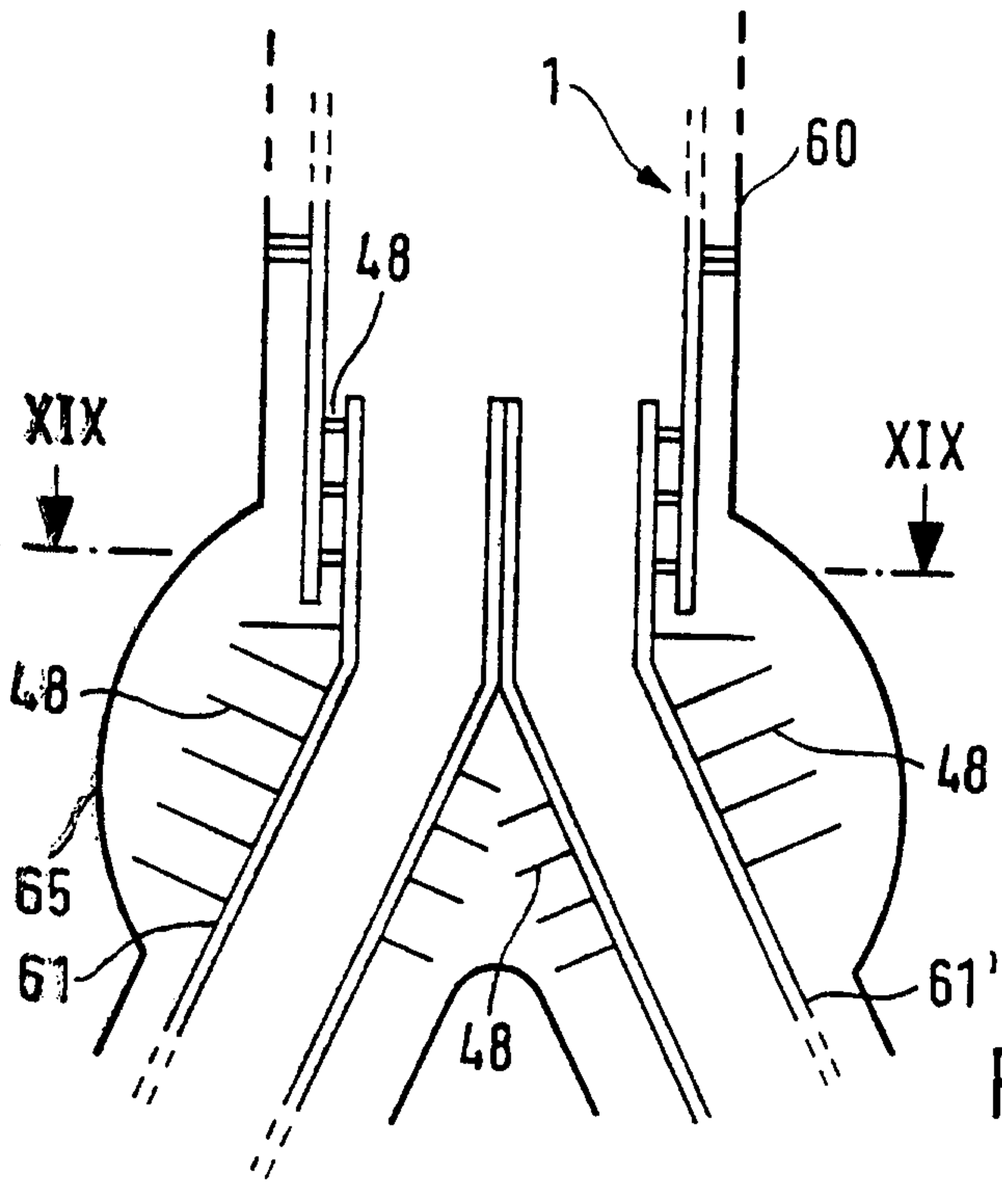


FIG.18

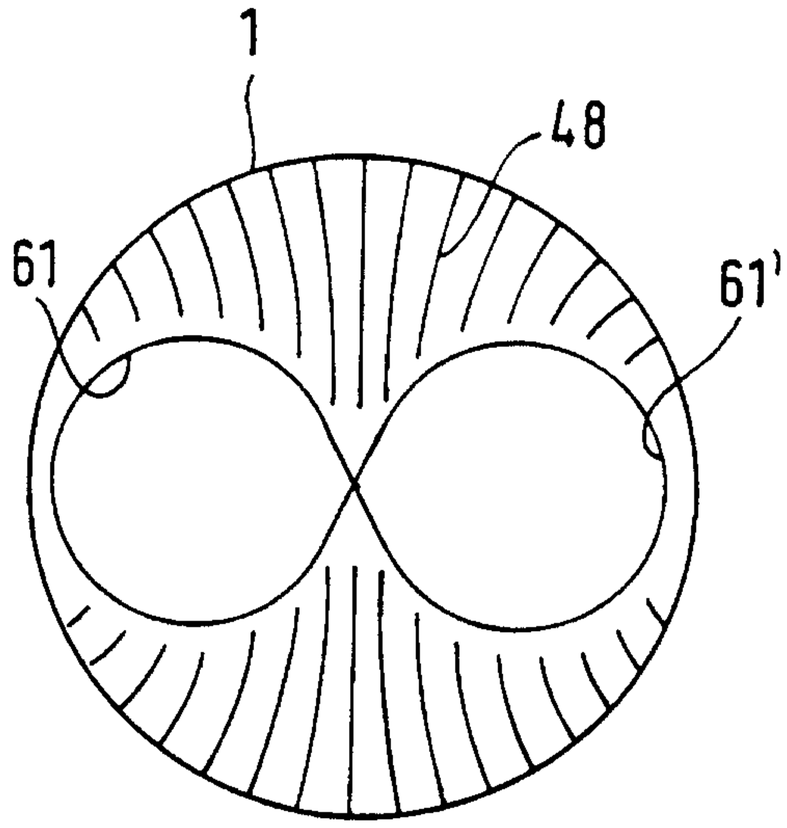


FIG.19

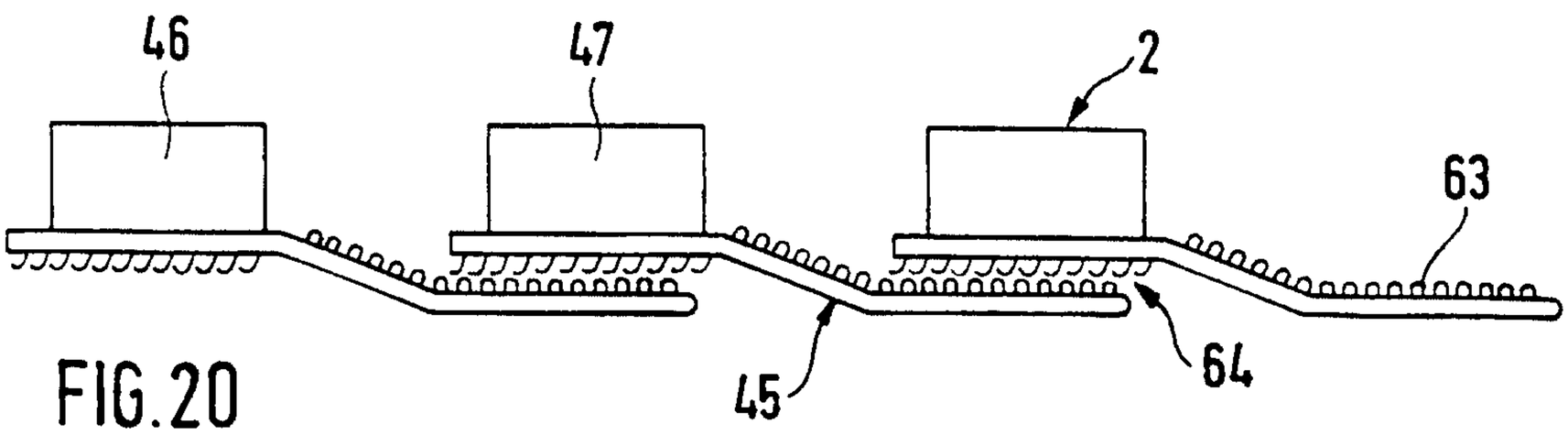


FIG.20

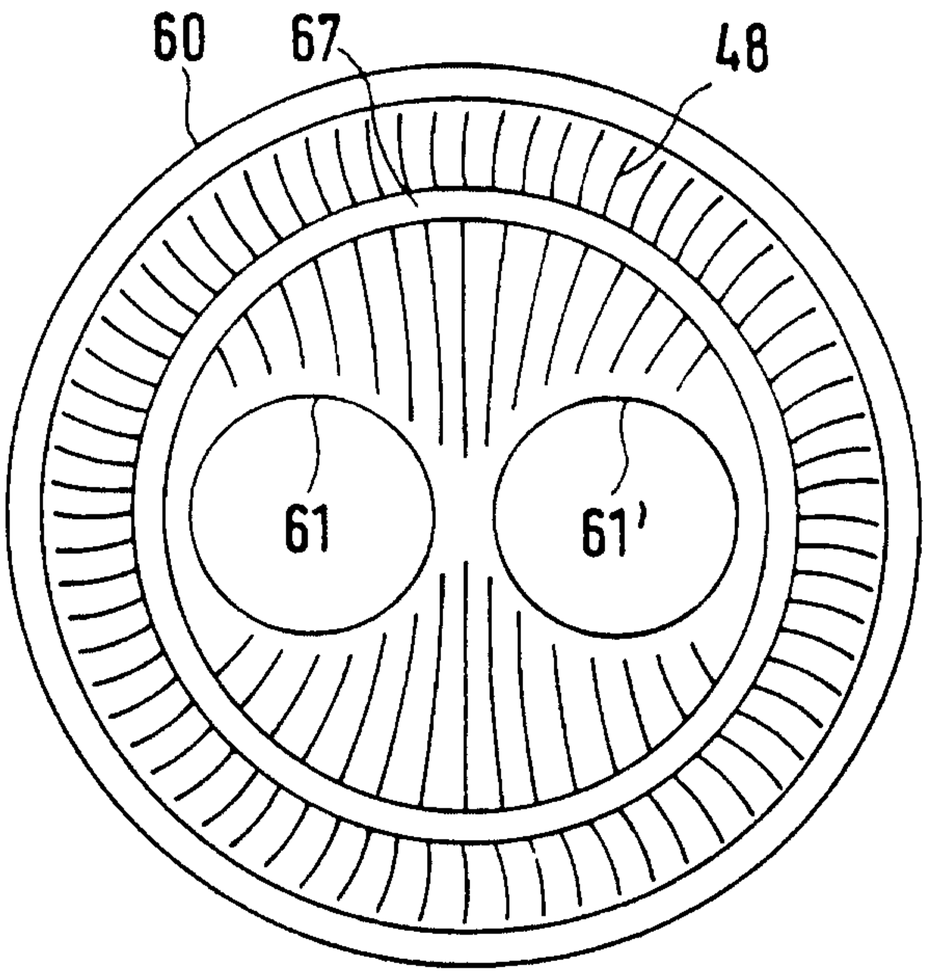


FIG.22

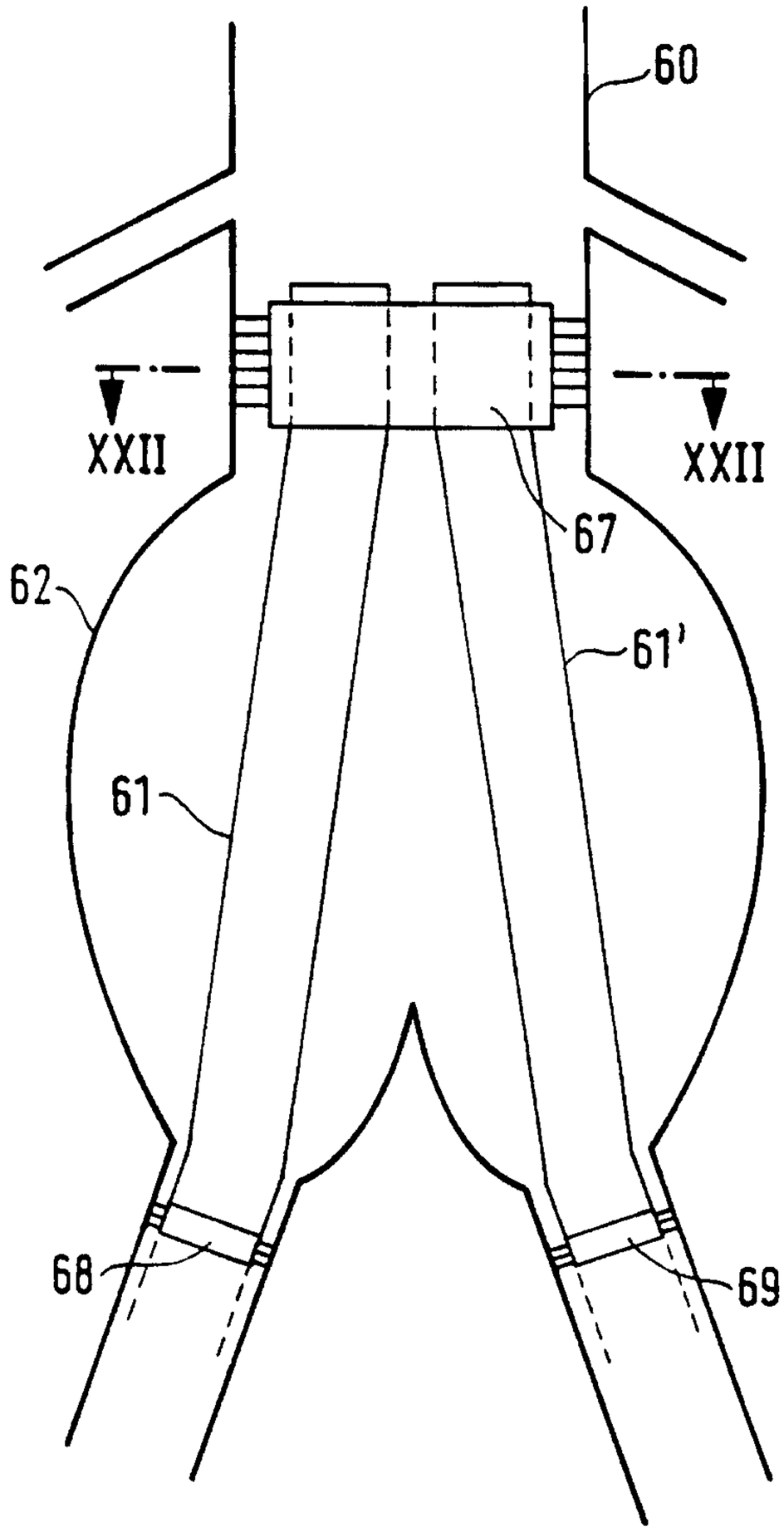


FIG.21

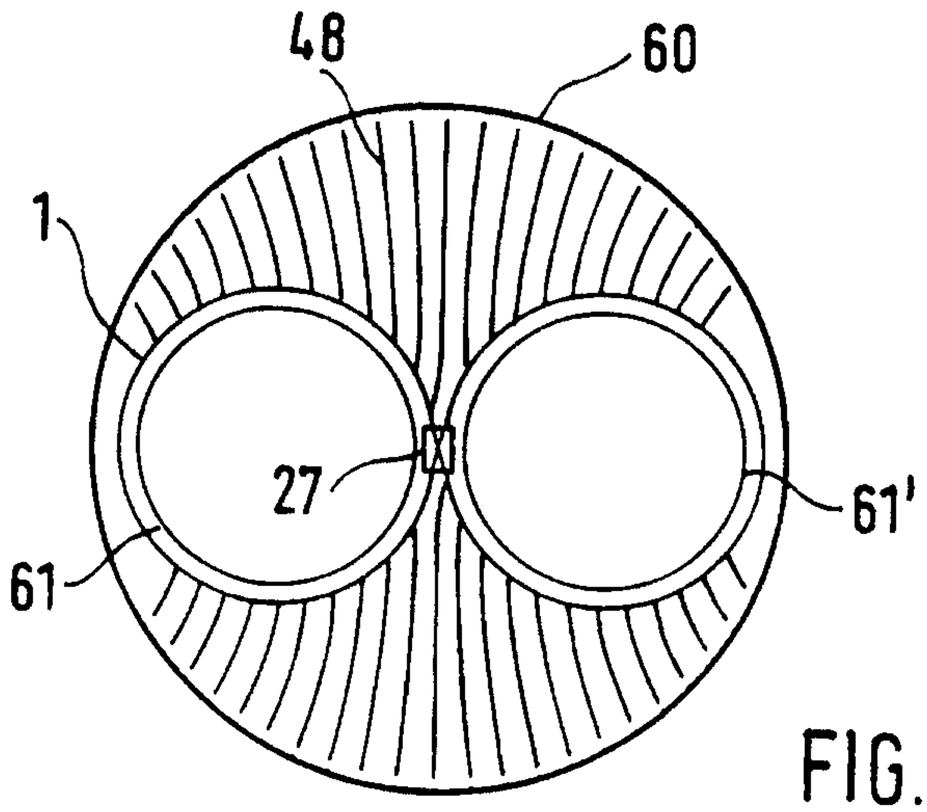


FIG. 24

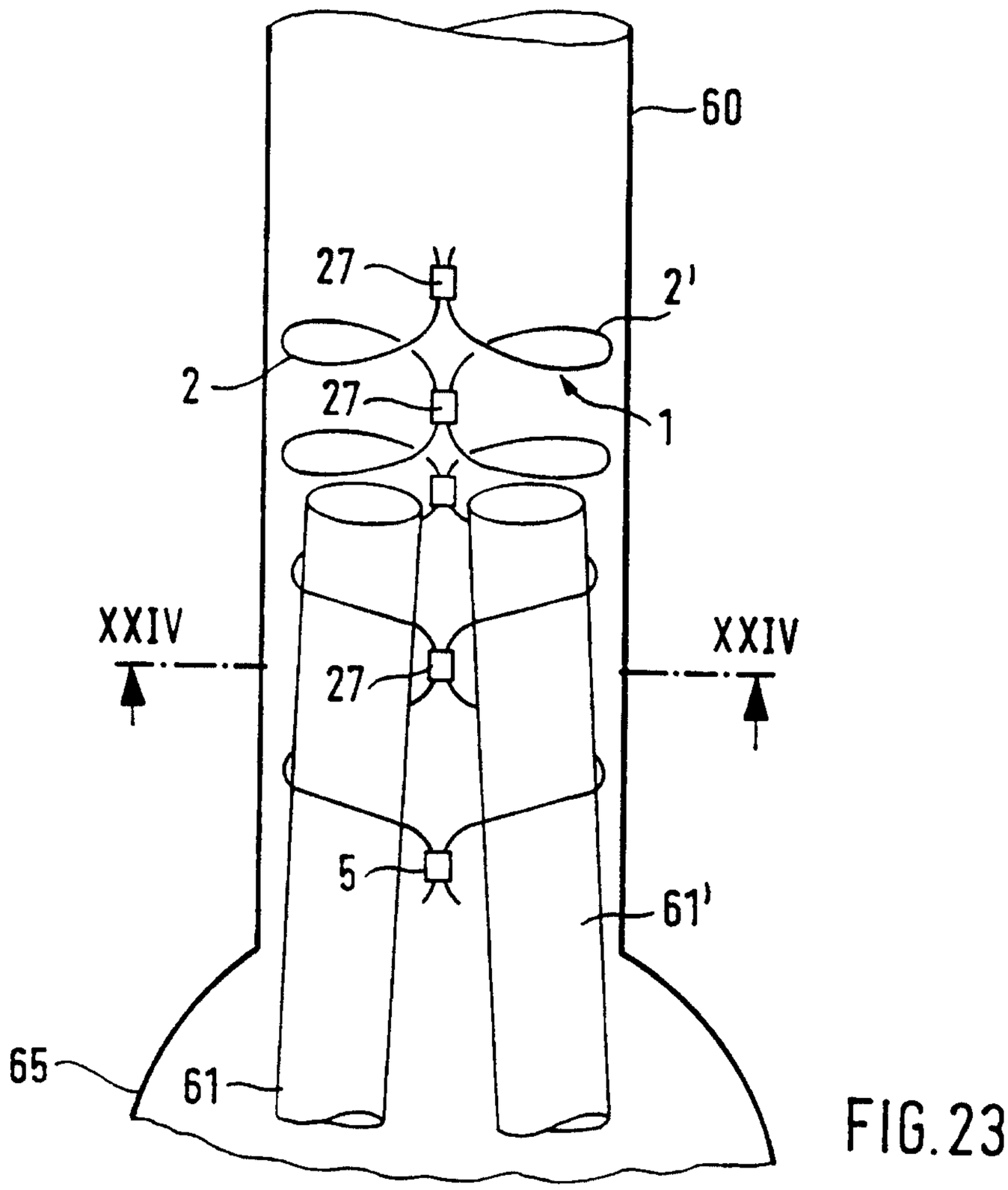


FIG. 23

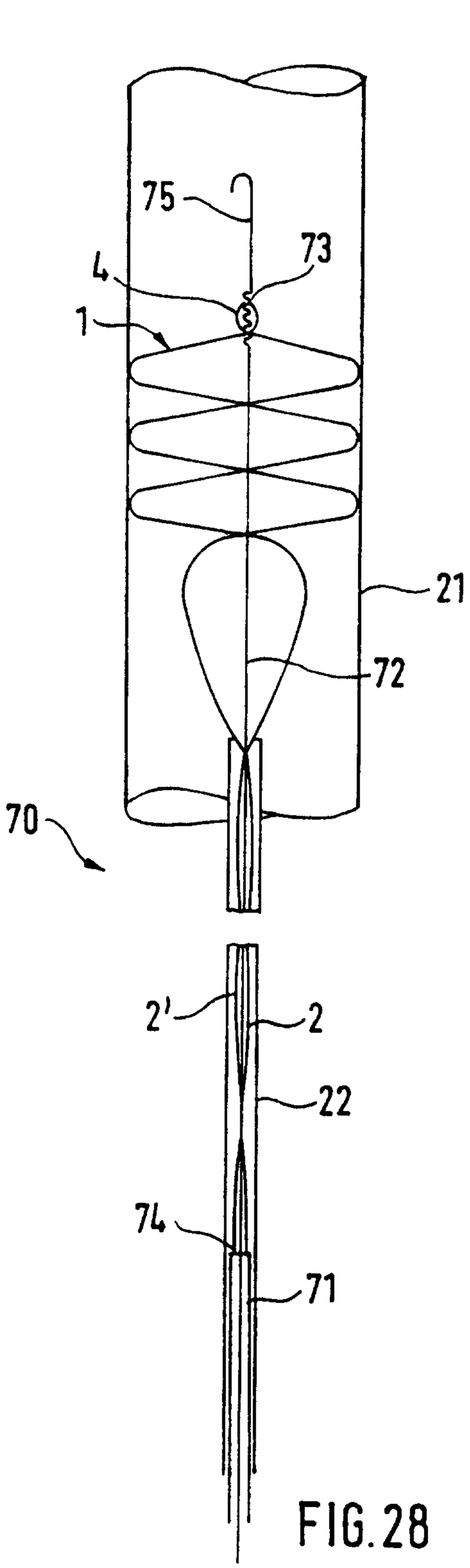


FIG. 28

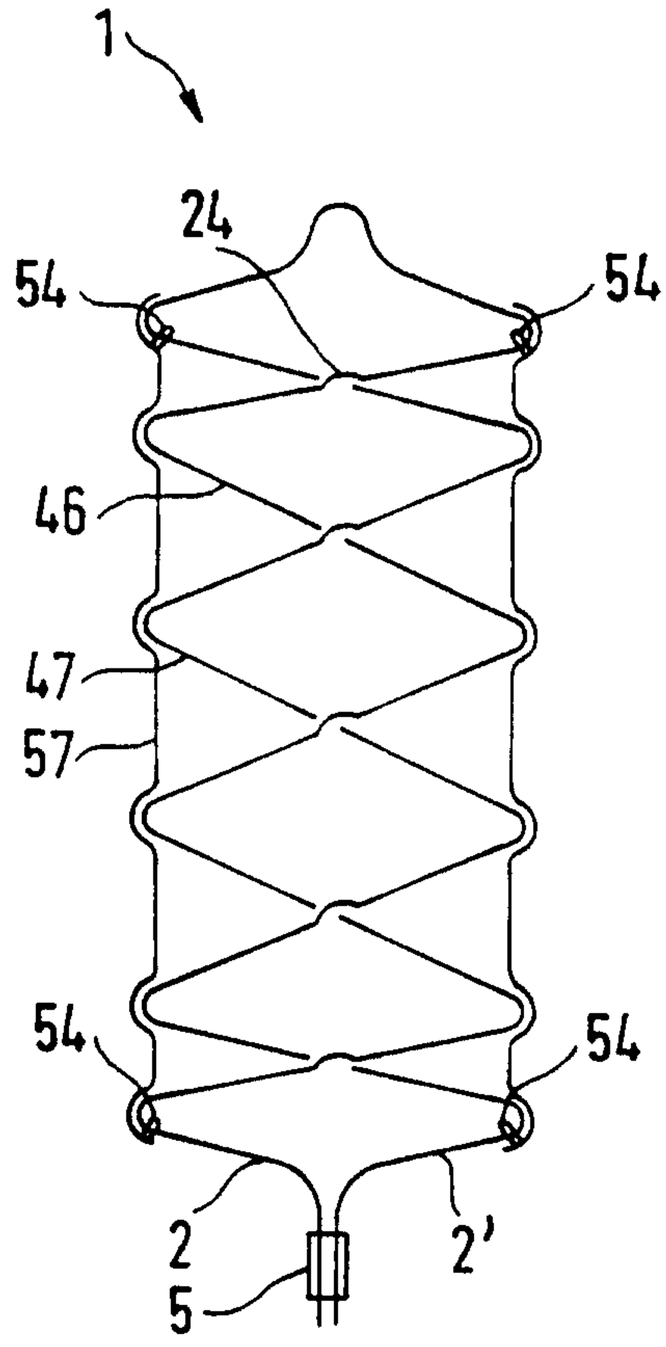


FIG. 25

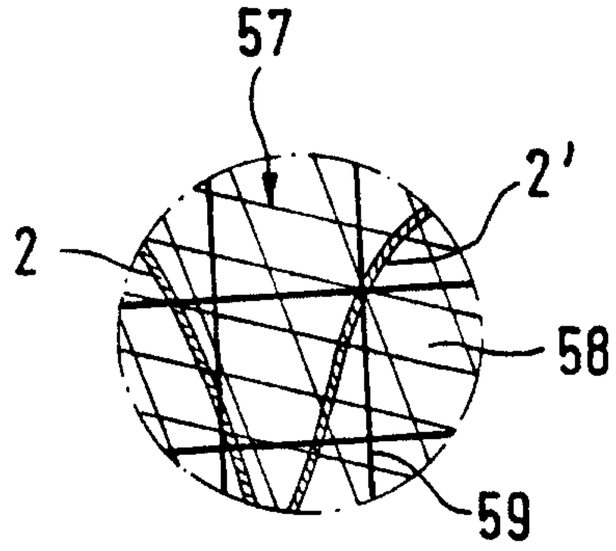


FIG. 26

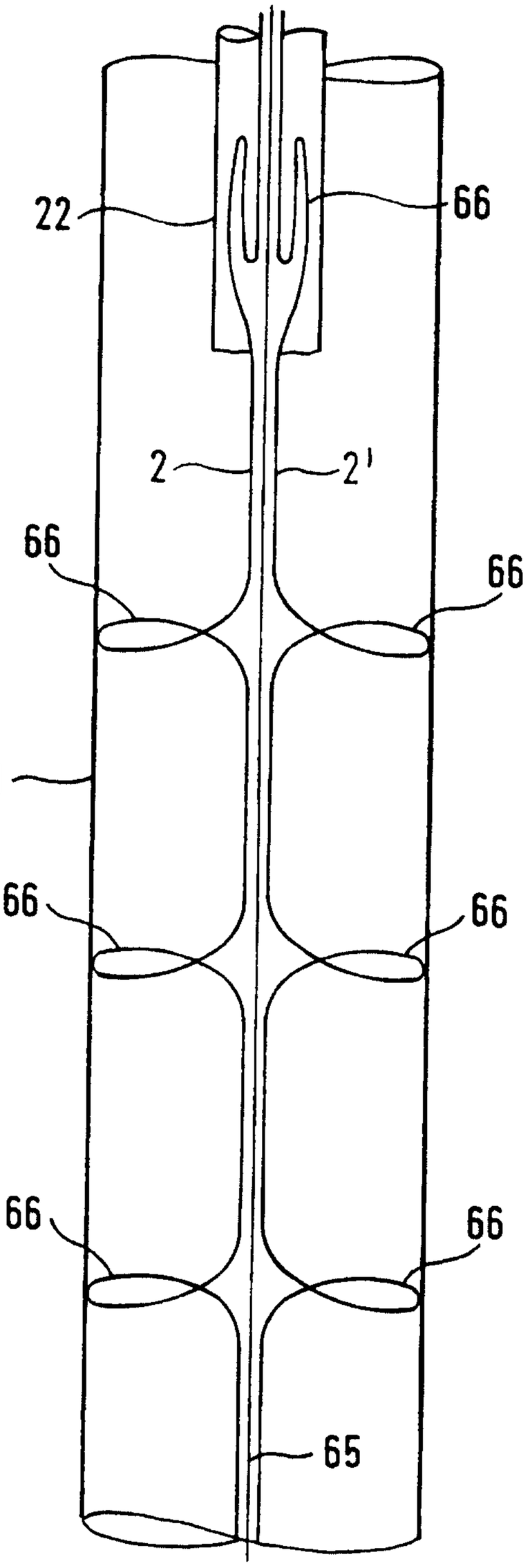


FIG. 27

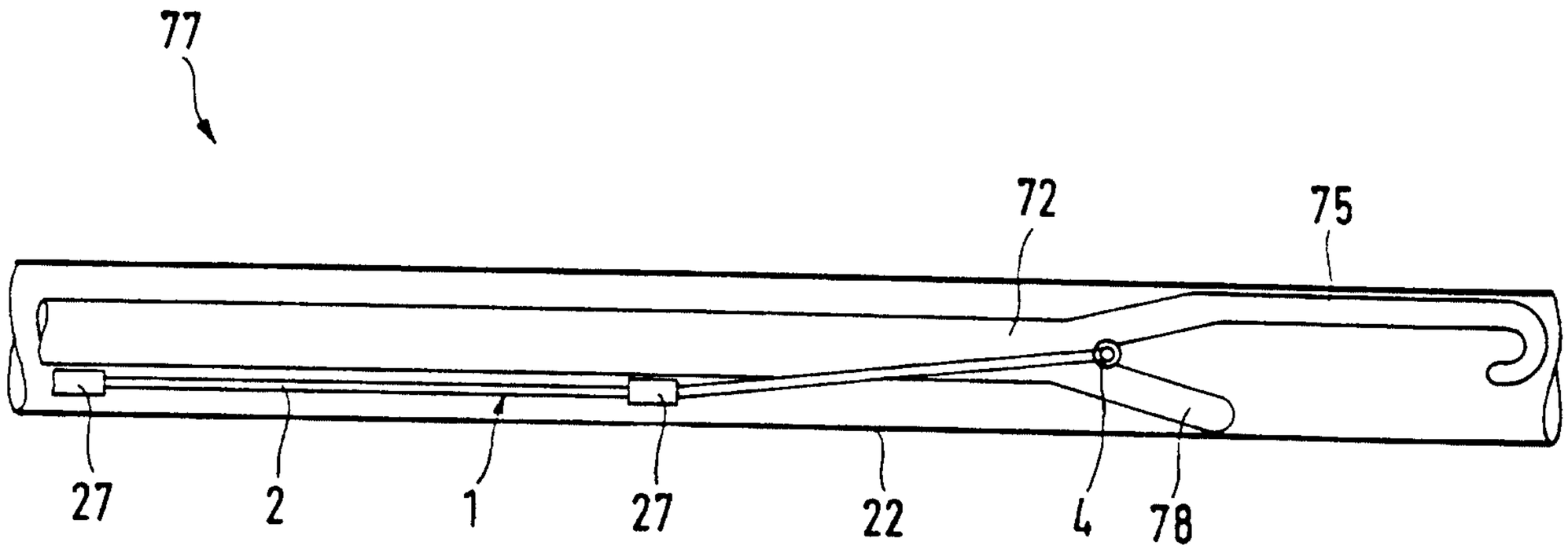


FIG. 29

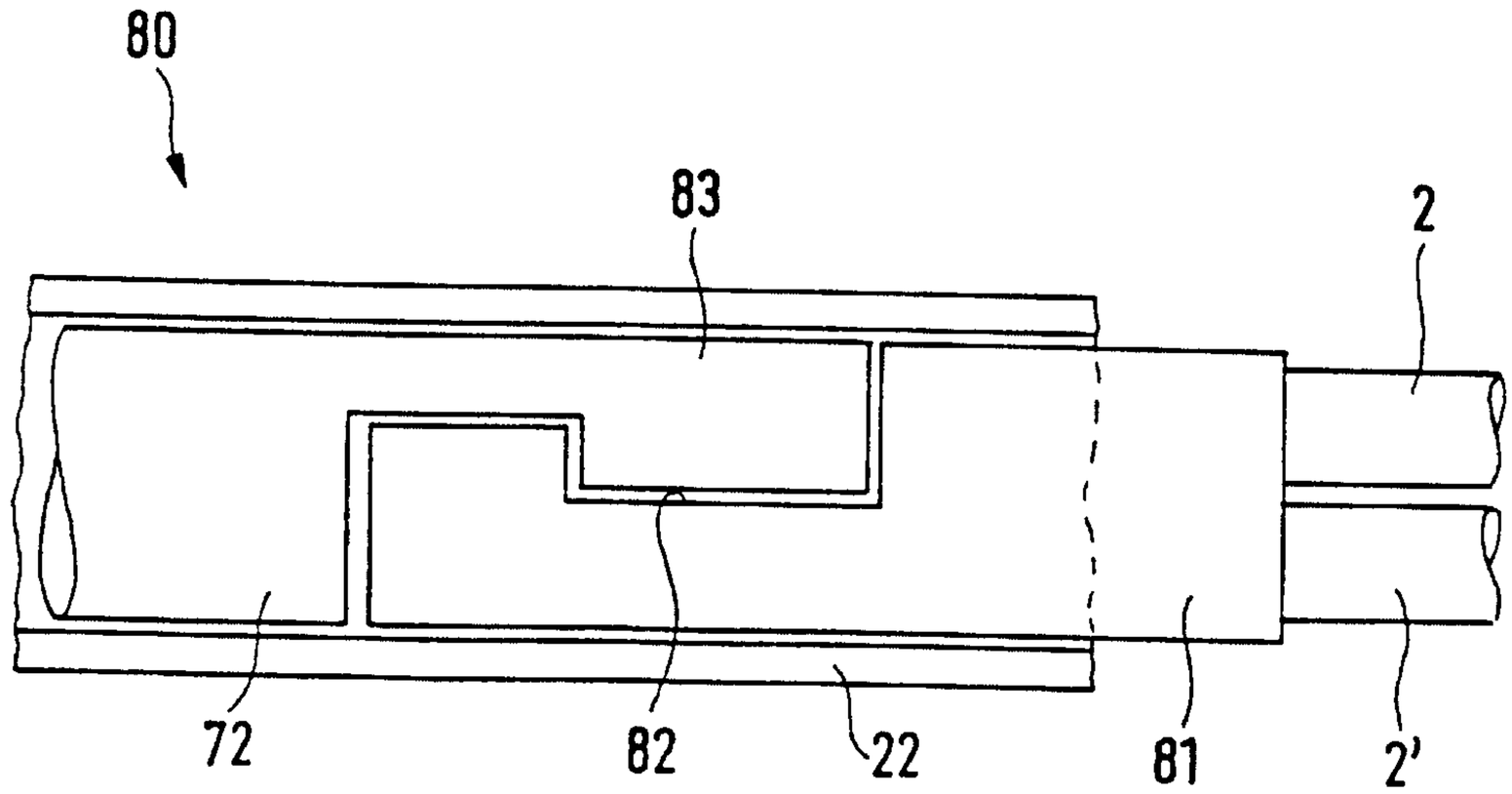


FIG. 30

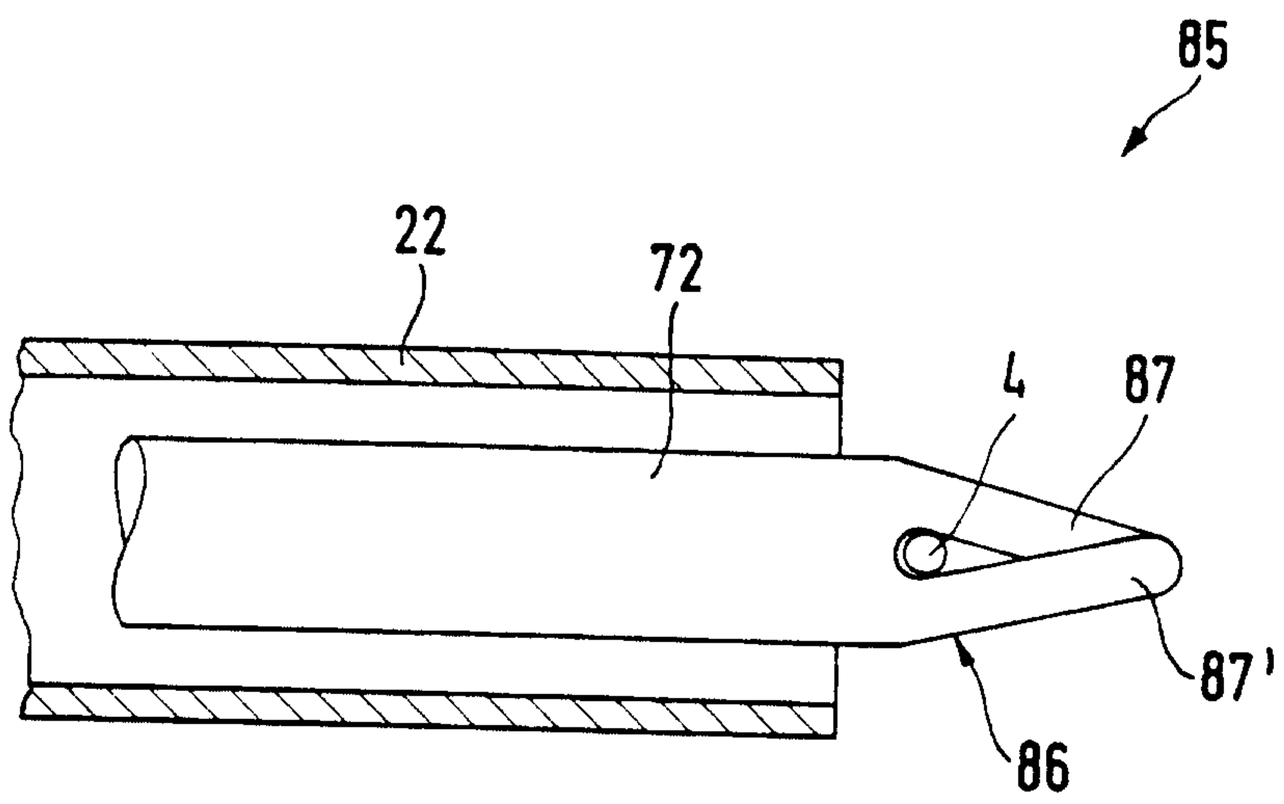


FIG. 31

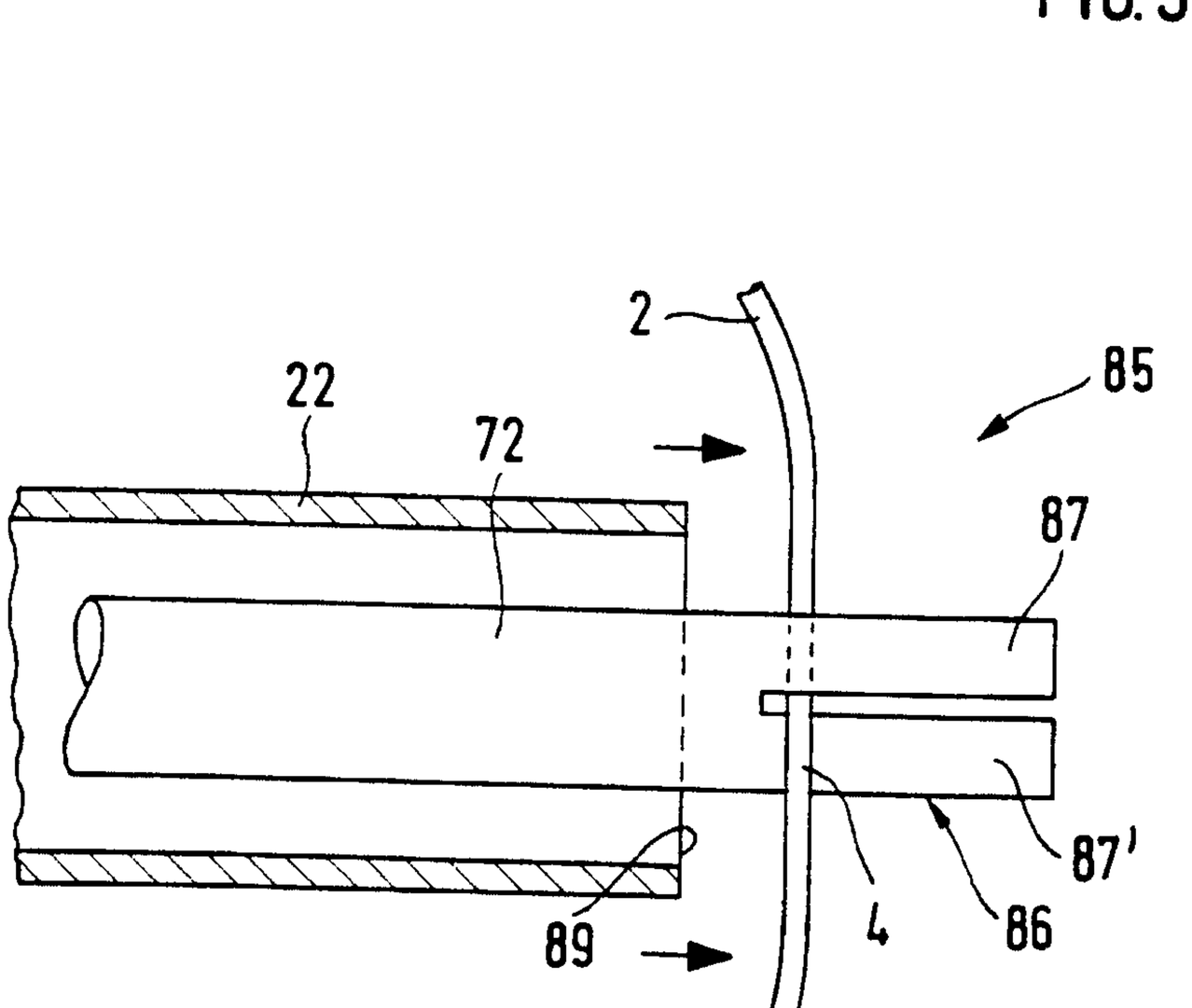
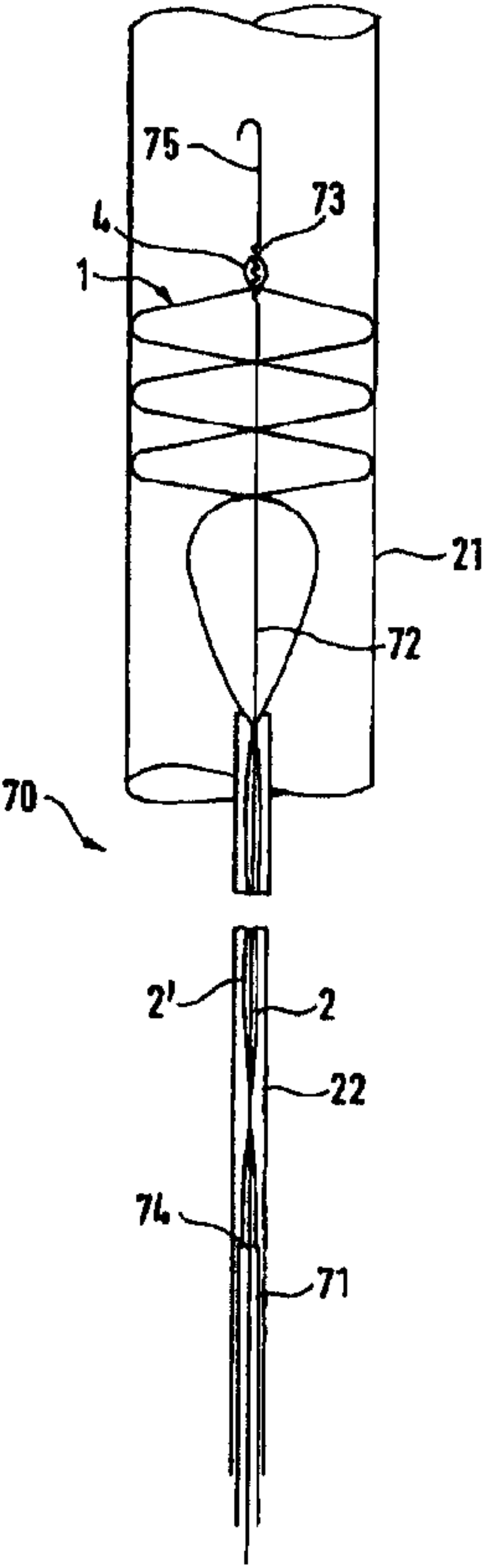


FIG. 32


75
73
4
1
21
72
70
2'
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74
71