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COMPAGNIE EUROPEENNE D'ETUDE ET DE RECHERCHE DE DISPOSITIFS POUR L'IMPLANTATION PAR LAPAROSCOPIE, FR

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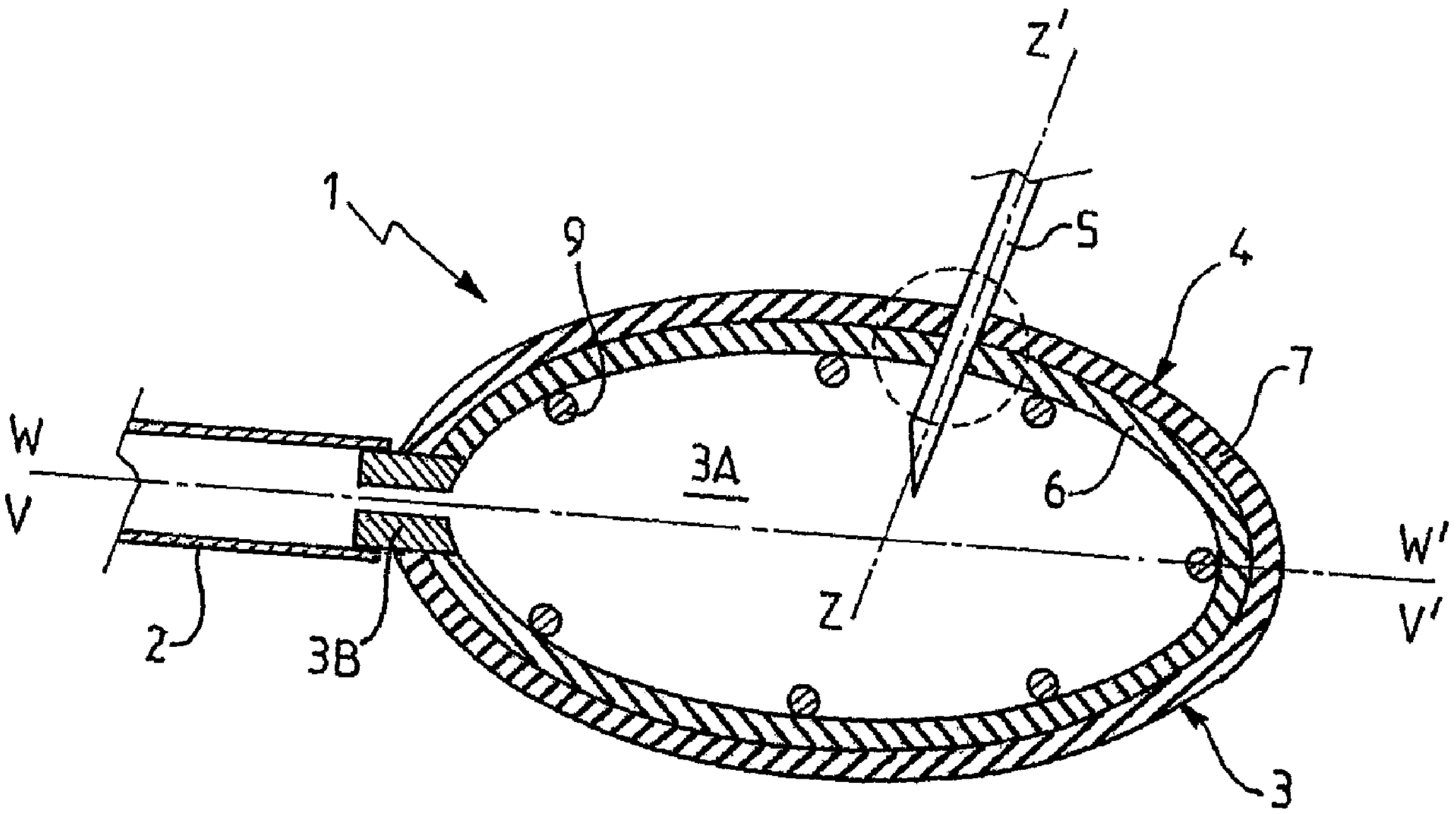


(57) Abrégé/Abstract:
The invention relates to an implantable device (1) for injecting and/or withdrawing fluid, comprising a housing (3) provided with a puncture area (4) configured in such a way that it can be pierced by a needle (5) in order to inject and/or withdraw fluid in a chamber (3A) fitted inside the housing, characterized in that said puncture area (4) comprises at least one and one second flexible membrane (6,7) which are superposed and freely mounted at least locally in relation to each other in order to enable, at least locally, displacement of one along the other such that the opening made by the needle (5) is divided up into sections of a first and second sub-opening (6A,7A) which do not coincide substantially in order to make the puncture area (4) substantially tight. Implantable medical sites.

A B S T R A C T

The invention relates to an implantable device (1) for injecting fluid and/or for tapping fluid, said device comprising a housing (3) provided with a puncture zone (4) designed to be suitable for being transpierced by a hollow needle (5) with a view to injecting fluid into and/or to tapping fluid from a chamber (3A) provided inside said housing (3), said implantable device being characterized in that said puncture zone (4) is made up of at least first and second superposed flexible membranes (6, 7) mounted to be free, at least locally, relative to each other, so as to allow them, at least locally, to move along each other, so that, once the needle (5) has been removed, the orifice formed by the needle (5) finds itself sliced into first and second sub-orifices (6A, 7A) substantially not coinciding so as to impart a substantially leaktight property to the puncture zone (4). The invention relates to medical implantable sites.

MEDICAL SITE WHICH CAN BE IMPLANTED IN A MULTILAYERED PUNCTURE AREA

TECHNICAL FIELD

The present invention relates to the general technical field of devices designed to be inserted surgically under the skin of a human or animal patient, for the purpose of being subsequently pierced with a hollow needle through the skin of the patient with a view to injecting substances into the body of the patient and/or to tapping substances from the body of the patient, while limiting reiterated injury to the skin at the same place. Such devices are generally referred to as "implantable sites" or as "access ports".

The present invention relates more particularly to an implantable device for injecting fluid into and/or for tapping fluid from either an organ or vessel of the body of a human or animal patient, or else an inflatable and/or deflatable compartment of a surgical implant, said device comprising a housing provided with a puncture zone designed to be suitable for being transpierced by a hollow needle with a view to injecting fluid into and/or to tapping fluid from a chamber provided inside said housing.

The present invention also relates to a method of manufacturing an implantable device for injecting fluid into and/or for tapping fluid from either an organ or vessel of the body of a human or animal patient, or else an inflatable and/or deflatable compartment of a surgical implant, said device comprising a housing provided with a puncture zone designed to be suitable for being transpierced by a hollow needle with a view to injecting fluid into and/or to tapping fluid from a chamber provided inside said housing.

PRIOR ART

Known implantable sites are generally in the form of a housing having a bottom from which there extend side walls whose free ends define a proximal opening. The bottom and the side walls are made of an uninterrupted and rigid material, such as titanium, in order to prevent them from being transpierced by a needle. The proximal opening is closed off by a membrane made of an elastomer material forming a "septum", i.e. a puncture zone suitable for being transpierced by a needle for the purpose of injecting fluid into or of tapping fluid from the internal volume of the housing defined by the bottom, by the side walls, and by the membrane.

In order to ensure that the housing is properly leaktight, the membrane made of elastomer is also generally of large thickness, e.g. of thickness greater than 4 mm. The membrane is also and above all compressed laterally in uniform manner, e.g. by forced hooping or binding by means of a metal ring, so as to impart self-closure (or self-healing) properties that are sufficient. In other words, once the needle has been removed from the membrane, said membrane, by means of the continuous internal stress to which it is subjected, immediately closes the hole corresponding to the needle passing through membrane.

Although such prior art sites are generally satisfactory, they also suffer from certain non-negligible drawbacks.

Firstly, because of the large thickness of the membrane that is necessary in order to impart appropriate leaktightness to the housing, known implantable sites are voluminous, which can contribute to making them uncomfortable for many patients, and in particular in patients of slight build, such as children.

In addition, known devices are generally difficult to manufacture, precisely because of the need to compress the

septum-forming membrane. The operation of assembling the membrane, i.e. of inserting the membrane into a ring so as to compress it, is thus, in general, difficult and poorly reproducible.

Finally, the need to compress the membrane significantly limits the possibilities of shaping the housing. In particular, currently known technology does not make it possible to obtain a site that can be pierced over a curved surface while also offering an excellent level of leaktightness for a large number of piercing operations (e.g. at least one thousand).

SUMMARY OF THE INVENTION

Objects assigned to the invention are thus to propose a novel implantable device for injecting and/or tapping fluid that makes it possible to remedy the various above-listed drawbacks, and that offers excellent leaktightness while also being compact and while offering a large degree of freedom for the geometrical shaping of the puncture zone.

Another object of the invention is to propose a novel implantable device for injecting and/or tapping fluid that is simple to manufacture.

Another object of the invention is to propose a novel implantable device for injecting and/or tapping fluid that is particularly light-weight, practical, and inexpensive.

Another object of the invention is to propose a novel implantable device for injecting and/or tapping fluid that reduces the risks and drawbacks related to bodily movements made by the patient.

Another object of the invention is to propose a novel implantable device for injecting and/or tapping fluid that does not need to be sutured to the body of the patient.

Another object of the invention is to propose a novel implantable device for injecting and/or tapping fluid that is particularly safe.

Another object of the invention is to propose a novel implantable device for injecting and/or tapping fluid whose leaktightness is particularly improved.

Another object of the invention is to propose a novel implantable device for injecting and/or tapping fluid that can be made using standard materials.

Another object of the invention is to propose a novel method of manufacturing an implantable device for injecting and/or tapping fluid that is extremely easy to implement.

Another object of the invention is to propose a novel method of manufacturing an implantable device for injecting and/or tapping fluid that is particularly quick and inexpensive.

The objects assigned to the invention are thus achieved by means of an implantable device for injecting fluid into and/or for tapping fluid from either an organ or vessel of the body of a human or animal patient, or else an inflatable and/or deflatable compartment of a surgical implant, said device comprising a housing provided with a puncture zone designed to be suitable for being transpierced by a hollow needle with a view to injecting fluid into and/or to tapping fluid from a chamber provided inside said housing, said implantable device being characterized in that said puncture zone is made up of at least first and second superposed flexible membranes mounted to be free, at least locally, relative to each other, so as to allow them, at least locally, to move along each other, so that, once the needle (5) has been removed, the orifice formed by the needle (5) finds itself sliced into first and second sub-orifices (6A, 7A) formed in respective ones of the first and second membranes (6, 7) and substantially not coinciding so as to

impart a substantially leaktight property to the puncture zone (4).

The objects assigned to the invention are also achieved by means of a method of manufacturing an implantable device for injecting fluid into and/or for tapping fluid from either an organ or vessel of the body of a human or animal patient, or else an inflatable and/or deflatable compartment of a surgical implant, said device comprising a housing provided with a puncture zone designed to be suitable for being transpierced by a hollow needle with a view to injecting fluid into and/or to tapping fluid from a chamber provided inside said housing, said method being characterized in that it includes a step of making said puncture zone, which step consists in superposing at least first and second flexible membranes mounted to be free, at least locally, relative to each other, so as to allow them, at least locally, to move along each other, so that, once the needle (5) has been removed, the orifice formed by the needle (5) finds itself sliced into first and second sub-orifices (6A, 7A) formed in respective ones of the first and second membranes (6, 7) and substantially not coinciding so as to impart a substantially leaktight property to the puncture zone (4).

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and advantages of the invention will appear on reading the following description, and on examining the accompanying drawings which are given merely by way of non-limiting illustration and in which:

· Figure 1 is a diagrammatic longitudinal section view showing an implantable device of the invention while it is being perforated by a needled for the purpose of performing fluid injection or fluid removal;

· Figure 2 is a diagrammatic section view showing an enlarged detail of Figure 1;

· Figure 3 is a diagrammatic section view showing the Figure 2 detail once the needle has been removed from the device;

· Figure 4 is a diagrammatic section view showing an implementation detail of a second variant device of the invention;

· Figures 5 and 6 show, in chronological order, various steps in making the variant embodiment of the device that is shown in Figure 1;

· Figures 7 to 9 are diagrammatic perspective views showing variant embodiments of a device of the invention, said variants differing from one another in particular by the geometrical shapes of their puncture zones;

· Figure 10 is a diagrammatic section view showing a variant embodiment of a device of the invention, said variant differing from the variants of Figures 7 to 9 in particular by the geometrical shape of its puncture zone; and

· Figure 11 is a diagrammatic cross-section view of a variant embodiment of a device of the invention, said device being provided with a non-transpierceable screen disposed inside the chamber.

BEST MANNER OF IMPLEMENTING THE INVENTION

The invention relates to an implantable device 1 for injecting and/or tapping a fluid. Such a device, which can also be referred to as an "implantable site", is designed to be implanted surgically into the body of a patient, and in particular under the skin of said patient, with a view to constituting an access port for inserting or for extracting fluid substances, in particular fluid substances of the

liquid type or of the pseudo-liquid type, into or from the body of said patient, who can be a human or an animal.

The implantable device 1 of the invention can be implemented and adapted for various uses. For example, the implantable device 1 of the invention can be designed for injecting fluid into and/or for tapping fluid from an organ or vessel of the body of a patient, and in particular the venous and/or arterial system of said patient. In such a use, which is known per se, the device 1 of the invention makes it possible, for example, to inject liquid medicinal substances into a vein or artery. The device 1 of the invention can also be adapted to feed implanted reservoirs, of the insulin pump or analgesic pump types. In another particular embodiment, the device 1 of the invention is specially adapted to form an artificial vein (or an artificial artery) that the practitioner, physician, or nurse can pierce as if it were a natural vein for the purpose of injecting a medicinal substance or of taking blood.

The implantable device 1 of the invention can also be adapted to inject and/or to tap fluid, such as physiological saline solution, into and/or from an inflatable and/or deflatable compartment of a surgical implant, and in particular of a gastroplasty band designed to treat obesity. Such a gastric band is known per se, and it is generally formed by a flexible strip designed to be looped back around the stomach and closed substantially in the vicinities of and via its two ends, by means of a closure system, in order to reduce the diameter of the opening of the stoma. Said strip can have an annular compression chamber of adjustable volume, connected via a catheter 2 to an implantable device 1 of the invention, which device makes it possible to adjust the internal volume of the chamber, in order to adjust the diametrical expansion thereof. However, the device of the

present invention can be used to adjust other surgical implants, such as, for example, artificial sphincters or balloons.

Reference is made below more particularly to a hypodermic device, i.e. a device designed to be positioned just under the skin of the patient. However, the device of the invention can be implanted at other places of the body of the patient, and, for example, deeper.

In accordance with the invention, the implantable device 1 comprises a housing 3 inside which a chamber is provided, which chamber is closed, preferably in liquid-tight manner. The housing 3 is advantageously provided with a duct 3B connecting the chamber 3A to the outside of the device 1. The duct 3B is itself preferably designed to be connected to a catheter 2, said catheter 2 being itself designed either to be connected to the organ or to the vessel into which fluid is to be injected or from which fluid is to be tapped, or else to be connected to the inflatable/deflatable compartment of a surgical implant.

In accordance with the invention, the housing 3 is provided with a puncture zone 4 designed to be suitable for being transpierced by a hollow needle 5, with a view to injecting fluid into the chamber 3A provided inside said housing 3 and/or to tapping fluid from said chamber.

The puncture zone 4 thus has the following properties:

· it is easily transpierceable by a hollow medical needle, such as, for example, a Hubert needle; and

· once the needle is removed, said puncture zone makes the chamber 3A leaktight, by preventing any leakage of liquid.

In other words, the puncture zone 4 must have a self-healing property, thereby preventing the liquid present in the chamber 3A from leaking out through the hole generated by the perforation formed by the needle 5.

According to an important characteristic of the invention, these self-healing and liquid-tight properties and obtained by means of the fact that the puncture zone 4 is made up of at least first and second superposed flexible membranes 6, 7 mounted to be free, at least locally, relative to each other, so as to allow them, at least locally, to move along each other. In other words, the puncture zone 4 is obtained by means of a first membrane 6 covered by at least one second membrane 7, said first and second membranes 6, 7 being, where they form the puncture zone 4, independent, i.e. not attached to each other, so as to enable them to slide relative to each other. It is precisely because of this capacity for the first and second membranes 6, 7 to move relative to each other that the orifice generated by inserting the needle 5 into the puncture zone 4 can be closed off automatically.

Since the first and second membranes 6, 7 are flexible, and preferably even elastic, each of said membranes 6, 7 deforms slightly in bending prior to being perforated, under the effect of the thrust exerted by the tip of the needle 5 along the perforation axis Z-Z'.

The membranes 6, 7 are thus transpierced while each of said membranes 6, 7 is in a geometrical shape that is distinct from the geometrical shape that it takes up at rest, i.e. in the absence of mechanical stress from a needle. In the rest configuration, each membrane 6, 7 can be stressed in tension, or in compression, or indeed be subjected to almost no stress and be in a relaxed state. As shown in Figure 3, when, under the effect of the needle 5 being removed from the puncture zone, the membranes 6, 7 resume their rest configuration, the orifice formed by the needle 5 in the puncture zone 4 then finds itself sliced into two sub-orifices 6A, 7A formed in respective ones of the first and second membranes 6, 7 and not coinciding (or

substantially not coinciding) so as to impart a substantially leaktight property to the puncture zone 4, i.e. so as substantially to prevent any leakage of fluid from the chamber 3A via the orifice formed by the needle 5.

In other words, under the effect of the membranes 6, 7 returning resiliently as allowed by the needle 5 being removed, the respective axes X-X' and Y-Y' along which the sub-orifices 6A, 7A extend become offset laterally, thereby breaking the communication between the chamber 3A and the outside. The sub-orifice 6A is closed off by the second membrane 7, while the sub-orifice 7A is closed off by the first membrane 6, each sub-orifice 6A, 7A thus forming a blind hole in the corresponding membrane. The first and second membranes 6, 7 are thus mounted relative to each other so that, once the needle 5 has been removed, the orifice formed by the needle 5 finds itself sliced into first and second sub-orifices 6A, 7A formed in respective ones of the first and second membranes (6, 7) and substantially not coinciding, the sub-orifice 6A being substantially closed off by the second membrane 7, while the sub-orifice 7A is substantially closed off by the first membrane 6.

The puncture zone 4 thus resumes a leaktight configuration at the place where it was perforated by the needle 5. The invention thus makes it possible, merely by pressing two flexible walls against each other, to obtain a self-closing puncture zone 4. Naturally, it is possible, with a view to optimizing the leaktightness of the device 1, to dispose more than two independent membranes (at least locally) on one another, so as to fragment the orifice generated by the needle 5 penetrating into the puncture zone 4 into as many segments that are offset axially relative to one another, at least for some of them. It thus seems that the higher the number of membranes implemented, the higher

the statistical probability of interrupting the communication between the inside of the chamber 3A and the outside, by axially offsetting the sub-orifices.

Preferably, the first and/or second membranes 6, 7 is/are made of an elastomer material of the silicone type. In view of the leaktight property of the silicone-on-silicone contact, it is particularly advantageous to make each membrane 6, 7 of silicone, in order to optimize the leaktightness at the interface 14 between each membrane. It is also possible to implement membranes each made of a silicone whose physical properties (e.g. elasticity, hardness, etc.) differ from the physical properties of the silicones used for making the other membranes. It can be particularly advantageous for the elasticity (or the hardness) of each membrane 6, 7 to be different from the elasticity (or the hardness) of each of the other membranes in order obtain a behavior gradient over the thickness of the puncture zone 4, which gradient contributes to offsetting the sub-orifices 6A, 7A relative to each other. Naturally, it is also possible to implement any material other than silicone, and in particular any material suitable for being transpierced by a needle and presenting flexibility and impermeability characteristics that are sufficient for contributing to forming the puncture zone 4.

It is also possible, as shown in Figure 4, to dispose between each membrane, namely, in this example, between the first and second membranes 6, 7, a layer 8 of a liquid-absorbent substance. The presence of such a layer 8 makes it possible to reinforce the leaktightness effect procured by the first and second membranes 6, 7 moving relative to each other. The layer 8 makes it possible to absorb and thus to retain any fraction of liquid that might find its way from the first sub-orifice 6A to the second sub-orifice 7A along the interface 14 of the first and second membranes

6, 7. Preferably, the layer 8 of absorbent substance is thin enough to enable the first sub-orifice 6A to be closed off by the second membrane 7 and vice-versa (to enable the second sub-orifice 7A to be closed off by the first membrane 6). In other words, the layer 8 of absorbent substance is advantageously in the form of a film, or of a thin sheet that does not provide the leaktightness directly by itself. Advantageously, the absorbent substance from which the layer 8 is made is chosen from one of the following substances and their derivatives: super-absorbent materials, polyvinyl alcohol (PVA) foams, and hydrophilic gels. This list is naturally non-limiting, any absorbent material of the foam or sponge type being quite suitable for implementing the layer 8.

Advantageously, at least one layer 80 of a lubricant substance is disposed between the first membrane 6 and the second membrane 7. The function of such a layer 80 is, in particular, to make it easier for the membranes 6, 7 to slide relative to each other, in order to make it easier for the sub-orifices 6A, 7A to be offset relative to each other, thereby making it possible to impart a leaktight property to the puncture zone 4. The layer 80 of lubricant substance is thin enough to enable the first sub-orifice 6A to be closed off by the second membrane 7 and vice versa (to enable the second sub-orifice 7A to be closed off by the first membrane 6). In other words the layer 80 of lubricant substrate is advantageously in the form of a film, or of a thin sheet, that does not provide leaktightness directly by itself. Advantageously, the layer 80 of lubricant substance comprises a lubricant coating deposited on either one or both of the membranes 6, 7. Preferably, each face of the membranes 6, 7 that is designed to find itself facing the other one is covered, e.g. uniformly, with a lubricant coating (e.g. a solid coating)so as to form coated membranes

6, 7 so that relative sliding of said coated membranes is facilitated. For example, said lubricant layer can be based on a coating of a polymer or the like, and in particular based on a coating of a material known by the trade name of Parylene.

Naturally, any other material or surface treatment that is known to the person skilled in the art could also be suitable. The lubricant layer could, in particular, not be formed of a solid coating attached to either of the membranes 6, 7 as described above, but rather be constituted by a thin film of (viscous) fluid interposed between the membranes 6, 7.

It is also possible to use a substance that is both absorbent and lubricant, in order thus to obtain a dual-purpose layer 8, 80 (cf. Figure 4).

In a preferred variant embodiment, the housing 3 includes a perforated skeleton 9, i.e. an open framework forming the structure of the housing 3 and imparting to said housing its overall shape. The skeleton 9 advantageously has rigid or semi-rigid properties, and is preferably made of a material that is substantially non-transpiercable by the needle 5. As shown in Figures 5 and 6, the skeleton 9 advantageously comprises a latticework of wires or filaments 90, e.g. made of metal or of substantially rigid plastic. Said latticework can, for example, be made by means of titanium wires, or result from molding a polymer. Advantageously, the skeleton 9 forms a three-dimensional structure that is convex in overall shape, and over which membranes 6, 7 are designed to be stretched. To this end, said first and second membranes 6, 7 are preferably in the form of respective ones of first and second first extensible sheaths 60, 70. The first sheath 60 covers the skeleton 9 so as to form therewith a sheathed skeleton 9A, over which

the second sheath 70 (cf. Figure 6) is force-fitted, by elastic deformation.

Advantageously, the first sheath 60 is also force fitted, by elastic deformation, over the skeleton 9. In other words, in the preferred embodiment shown in Figures 5 and 6, the skeleton 9 forms a reinforcing framework serving to support at least two membranes 6, 7 which are successively fitted over said skeleton 9 so as to take on the general shape thereof, by elastic deformation, in the manner of a sock put on a foot. The sheaths 60, 70 can be in the form of closed pouches that are open at one end only, so that they are suitable for being fitted over the reinforcing framework 9, or else in the form of sleeves, i.e. sheaths that are open at both opposite ends. Naturally, the sheaths 60, 70 are of general shape that is close to the shape of the skeleton 9 so that skeleton 9 being covered by the sheaths 60, 70 does not give rise to creases or to zones that are too slack, but rather facilitates substantially uniform tensioning of each sheath 60, 70 over the skeleton 9. In which case, the membranes 6, 7 are thus stretched over the reinforcing framework formed by the skeleton 9. However, it is quite possible for the membranes 6, 7 to be tensioned merely temporarily as they are being put in place on the skeleton 9, and are then in a relaxed state (i.e. a state in which stresses are relaxed), or indeed in a compressed state, once they are positioned on the skeleton 9.

The superposed sheaths 60, 70 co-operating with the skeleton 9 make it possible to form the puncture zone 4 because the needle 5 can transpierce the stack of membranes 6, 7 into the orifices provided in the surface of the skeleton 9, which orifices are defined, for example, by metal meshing or latticework that advantageously forms said skeleton 9.

Advantageously, the duct 3B connecting the chamber 3A to the outside of the device 1 extends longitudinally along a first axis V-V', the puncture zone 4 being substantially symmetrical relative to a second axis W-W' that is substantially parallel to and preferably coincides with the first axis V-V'. In this embodiment, which corresponds to the various variants shown in Figures 1 to 9 and 11, the housing 3, and preferably the puncture zone 4 itself, are preferably substantially circularly symmetrical about the second axis W-W', which axis coincides with the first axis V-V' in the direction in which the duct 3B extends.

Such an implantable device 1, whose puncture zone 4 is circularly symmetrical, is particularly comfortable for the patient because it does not need to be sutured to the biological tissues of the patient on being implanted. The suturing performed in the prior art is justified by the difficulties that could arise if the device 1 were to turn over under the skin of the patient, e.g. due to movements of said patient. Such turning over could give rise to the puncture zone 4 being masked, i.e. to it being impossible for a needle 5 to perforate it through the skin of the patient. Such a problem is solved completely by the device 1 of the variants of Figures 1 to 9 since, even if such a device does turn over under the skin of the patient, a portion of the puncture zone 4 always remains accessible to the needle 5 by means of the circular symmetry of said puncture zone 4.

Advantageously, the puncture zone 4 is spherical in overall shape, as is shown in Figure 7. Such a spherical puncture zone 4 can be obtained by implementing a skeleton 9 that itself is spherical in overall shape, and over which a series of sheaths are fitted, the sheaths themselves being in the form of spherical pouches each having one opening and

being suitable for being distended so that each sheath can be fitted successively over the spherical skeleton.

In another embodiment, corresponding to Figures 1 to 6, the puncture zone 4 is ovoid in overall shape, its major axis of symmetry W-W' extending substantially in the same direction as the direction V-V' in which the duct 3B extends. Such an ovoid puncture zone 4 is obtained, for example, as shown in Figures 5 and 6, by implementing an ellipsoidal latticework covered with a plurality of pouches that themselves have ellipsoidal shapes that are complementary to the shape of the latticework, so as to obtain an ovoid housing 3. Such an ovoid housing is particularly easy to insert under the skin of a patient, and is generally particularly well tolerated by said patient.

In another embodiment, the puncture zone 4 is substantially pear-shaped as shown in Figure 9. Preferably, the axis of symmetry of the pear-shaped zone 4 W-W' coincides with the axis V-V' along which the duct 3B extends. In a manner analogous to the manner described above, such a pear-shaped zone 4 can be obtained by covering a pear-shaped latticework with flexible pouches that have shapes complementary to the shape of the latticework.

In another variant embodiment, corresponding to Figure 8, the puncture zone 4 is cylindrical in overall shape. Such a cylindrical puncture zone 4 can, for example, be obtained by implementing a skeleton 9 that is itself cylindrical and over which a plurality of sleeves that are cylindrical and open at both opposite ends are fitted such that they are superposed on one another. It is also possible to imagine covering the cylindrical skeleton of the device corresponding to Figure 8 with pouches that have a single opening, unlike the above-mentioned sleeves that have two openings.

Advantageously, a screen 10 made of a material that is not transpierceable by the hollow needle 5 is disposed inside the housing, in order to prevent the housing 3 from being perforated through to the other side during transpiercing by the needle 5 (cf. Figure 11). Said screen 10 prevents the needle 5 from exiting from the chamber 3 to the outside the device 1, it being possible for such exiting to cause injury to the biological tissues around the device 1. In particular, the screen 10 is designed as a function of the shape of the puncture zone 4, so as to allow piercing that is effective and safe to be performed at any point on the puncture zone 4. Advantageously, the screen 10 comprises a bladed wheel 11 that is shaped and positioned such that said blades 11A, 11B, 11C, 11D extend substantially radially about the axis of symmetry W-W' of the puncture zone 4. Advantageously, there are at least four blades 11A, 11B, 11C and 11D that are preferably uniformly spaced apart angularly. Naturally, it is quite possible to imagine providing a lower or a higher number of blades, or even some other type of screen 10. In addition, the screen 10 is shaped so as to enable fluid communication or circulation to be established inside the chamber 3A. For example, in the example shown in Figure 10 in which the screen 10 is formed by a wheel having four blades 11A, 11B, 11C, 11D, the four compartments defined inside the chamber 3A by said blades 11A, 11B, 11C, 11D are not leaktight, and they are all in fluid communication, even indirectly, with one another. For this purpose, it is, for example, possible to dimension blades so that they do not fit snugly against the first membrane 5 forming the outline of the chamber 3A (in the variant shown in Figure 10). The screen 10 can float freely inside the chamber 3A, or optionally can be held in position by means of a fastening system. Naturally, the use of a screen 10 is purely optional.

The devices 1 described above are circularly symmetrical. However, it is quite possible for the device 1 to have a more conventional configuration, as shown in Figure 10. In which case, the housing 3 comprises a bottom 30, e.g. a disk-shaped bottom, from which a side wall 31 extends. Said bottom 30 and said wall 1 are preferably made of a material that is not transpierceable by a needle 5. Opposite from the bottom 30, the side wall 31 defines an opening closed off by a puncture zone 4 formed by a superposition of at least two and, for example, three (as shown in Figure 11) membranes 6, 7, 12. In accordance with the general concept of the invention, said first, second, and third membranes 6, 7, 12 are mounted to be free relative to one another and, for example, are held in position at their peripheries only, by the presence of a bottom rim 31A and of a top rim 31B, the rims extending inwards from the side wall 31, and being designed to clamp the stack of membranes 6, 7, 12 between them. Conventionally, the device shown in Figure 11 is provided with a duct 3B extending from the side wall 3A in a direction V-V' that is perpendicular to the axis of symmetry W-W' of the housing 3.

The invention also relates to a method of manufacturing an implantable device 1 for injecting fluid into and/or for tapping fluid from either an organ or vessel of the body of a human or animal patient, or else an inflatable and/or deflatable compartment of a surgical implant, said device 1 comprising a housing 3 provided with a puncture zone 4 designed to be suitable for being transpierced by a hollow needle 5 with a view to injecting fluid into and/or to tapping fluid from a chamber 3A provided inside said housing 3.

According to an important characteristic of the invention, said method includes a step of making said puncture zone 4, which step consists in superposing at least

first and second flexible membranes 6, 7 mounted to be free, at least locally, relative to each other, so as to allow them, at least locally, to move along each other, so that, once the needle 5 has been removed, the orifice formed by the needle 5 finds itself sliced into first and second sub-orifices 6A, 7A formed in respective ones of the first and second membranes 6, 7 and substantially not coinciding so as to impart a substantially leaktight property to the puncture zone 4.

Advantageously, the first and second membranes 6, 7 are mounted relative to each another so that said first sub-orifice 6A is substantially closed off by the second membrane 7 and vice versa once the needle 5 is removed.

Advantageously, the method of the invention includes an interposition step consisting in interposing between each membrane 6, 7 a layer 80 of lubricant substance. Preferably, said interposition step comprises a deposition step consisting in depositing a coating of lubricant (such as, for example, Parylene®) on either one or both of the membranes 6, 7, said coating being preferably uniform and secured to the membrane 6, 7 in question. It is also possible, as described above, for the lubricant layer 80 to be in the form of thin viscous film independent from the membranes 6, 7 and interposed therebetween.

Advantageously, the method of the invention includes a manufacturing step for manufacturing the housing 3, which step consists in providing or manufacturing a perforated skeleton 9. Advantageously, the step of making the puncture zone 4 consists in providing or manufacturing first and second extensible sheaths 60, 70 that form respective ones of the first and second membranes 6, 7 and in covering the skeleton 9 with the first sheath 60 so as to form a sheathed skeleton 9A, and then in force-fitting the second sheath 70 over said sheathed skeleton.

The above-described method can advantageously constitute a method of manufacturing an implantable device for injecting inflation fluid into and/or tapping inflation fluid from an inflatable and/or deflatable compartment of a gastroplasty band designed for treating obesity. The method of the invention can alternatively constitute a method of manufacturing an implantable device for injecting a medicinal substance into a vein or an artery and/or for removing blood from said vein or artery, said device 1 thus forming an artificial vein or an artificial artery.

The invention makes it possible to obtain an implantable site offering excellent leaktightness without implementing a large thickness of silicone which is necessary for prior art septa. The principle of the invention makes it possible, by means of a stack of very thin membranes, to obtain a puncture zone that, in spite of its small thickness, offers an excellent self-healing property.

The invention also makes it possible to solve the problem of leaktightness of an implantable site whose puncture zone is circularly symmetrical. The geometrical shapes of such sites prevent prior art solutions to that problem from being used, such prior solutions involving uniformly and radially compressing a thick block of silicone.

Finally, the invention makes it possible, extremely simply, to obtain an implantable device 1 that offers the above-mentioned advantages, by means of a manufacturing method that is easy and quick to implement.

SUSCEPTIBILITY OF INDUSTRIAL APPLICATION

The invention is susceptible of industrial application in designing, manufacturing, and using implantable devices for injecting and/tapping fluid.

CLAIMS

1. An implantable device (1) for injecting fluid into and/or for tapping fluid from either an organ or vessel of the body of a human or animal patient, or else an inflatable and/or deflatable compartment of a surgical implant, said device (1) comprising a housing (3) provided with a puncture zone (4) designed to be suitable for being transpierced by a hollow needle (5) with a view to injecting fluid into and/or to tapping fluid from a chamber (3A) provided inside said housing (3), said implantable device being characterized in that said puncture zone (4) is made up of at least first and second superposed flexible membranes (6, 7) mounted to be free, at least locally, relative to each other, so as to allow them, at least locally, to move along each other, so that, once the needle (5) has been removed, the orifice formed by the needle (5) finds itself sliced into first and second sub-orifices (6A, 7A) formed in respective ones of the first and second membranes (6, 7) and substantially not coinciding so as to impart a substantially leaktight property to the puncture zone (4).

2. A device according to claim 1, characterized in that the first and second membranes (6, 7) are mounted relative to each other such that said first sub-orifice (6A) is substantially closed off by the second membrane (7) once the needle (5) has been removed.

3. A device (1) according to claim 1 or claim 2, characterized in that the housing (3) includes a perforated skeleton (9), said first and second membranes (6, 7) being in the form of respective ones of first and second extensible sheaths (60, 70), the first sheath (60) covering the skeleton (9) so as to form therewith a sheathed skeleton (9A) over which the second sheath (70) is force-fitted.

4. A device (1) according to claim 3, characterized in that the skeleton (9) comprises a latticework (90) of substantially rigid wires or filaments.

5. A device (1) according to any one of claims 1 to 4, characterized in that the puncture zone (4) has one of the following shapes: a substantially spherical shape, a substantially ovoid shape, a substantially pear-shaped shape, or a substantially cylindrical shape.

6. A device (1) according to any one of claims 1 to 5, characterized in that at least one layer (8) of a liquid absorbent substance is disposed between the first membrane (6) and the second membrane (7).

7. A device (1) according to claim 6, characterized in that the absorbent substance is chosen from any one of the following substances and their derivatives: super-absorbent materials, polyvinyl alcohol (PVA) foams, and hydrophilic gels.

8. A device (1) according to any one of claims 1 to 7, characterized in that at least one layer (80) of a lubricant substance is disposed between the first membrane (6) and the second membrane (7).

9. A device according to claim 8, characterized in that the layer (80) of lubricant substance comprises a coating of lubricant deposited on either one or both of the membranes (6, 7).

10. A device (1) according to any one of claims 1 to 9, characterized in that the first and/or the second

membrane(s) (6, 7) are based on an elastomer material of the silicone type.

11. A device (1) according to any one of claims 1 to 10, characterized in that it forms an implantable device for injecting inflation fluid into and/or for tapping inflation fluid from an inflatable and/or deflatable compartment of a gastroplasty band.

12. An implantable device (1) according to any one of claims 1 to 10, for injecting a medicinal substance into a vein or artery and/or for taking blood from said vein or artery, thereby forming an artificial vein or an artificial artery.

13. A method of manufacturing an implantable device (1) for injecting fluid into and/or for tapping fluid from either an organ or vessel of the body of a human or animal patient, or else an inflatable and/or deflatable compartment of a surgical implant, said device comprising a housing (3) provided with a puncture zone (4) designed to be suitable for being transpierced by a hollow needle (5) with a view to injecting fluid into and/or to tapping fluid from a chamber (3A) provided inside said housing (3), said method being characterized in that it includes a step of making said puncture zone (4), which step consists in superposing at least first and second flexible membranes (6, 7) mounted to be free, at least locally, relative to each other, so as to allow them, at least locally, to move along each other, so that, once the needle (5) has been removed, the orifice formed by the needle (5) finds itself sliced into first and second sub-orifices (6A, 7A) formed in respective ones of the first and second membranes (6, 7) and substantially not coinciding so as to impart a substantially leaktight property to the puncture zone (4).

14. A method according to claim 13, characterized in that the first and second membranes (6, 7) are mounted relative to each other such that said first sub-orifice (6A) is substantially closed off by the second membrane (7) once the needle (5) has been removed.

15. A method according to claim 13 or claim 14, characterized in that it includes a manufacturing step for manufacturing the housing (3), which step consists in providing or manufacturing a perforated skeleton (9), and in that, the step of making the puncture zone (4) consists in providing or manufacturing first and second extensible sheaths (60, 70) that form respective ones of the first and second membranes (6, 7) and in covering the skeleton (9) with the first sheath (60) so as to form a sheathed skeleton (9A), and then in force-fitting the second sheath (70) over said sheathed skeleton.

16. A method according to any one of claims 13 to 15, characterized in that it includes an interposition step consisting in interposing between each membrane (6, 7) a layer (80) of lubricant substance.

17. A method according to claim 16, characterized in that said interposition step comprises a deposition step consisting in depositing a coating of lubricant on either one or both of the membranes (6, 7).

18. A method according to any one of claims 13 to 17, characterized in that it constitutes a method of manufacturing an implantable device (1) for injecting inflation fluid into and/or tapping inflation fluid from an

inflatable and/or deflatable compartment of a gastroplasty band.

19. A method according to any one of claims 13 to 17, characterized in that it constitutes a method of manufacturing an implantable device (1) for injecting a medicinal substance into a vein or an artery and/or for removing blood from said vein or artery, said device thus forming an artificial vein or an artificial artery.

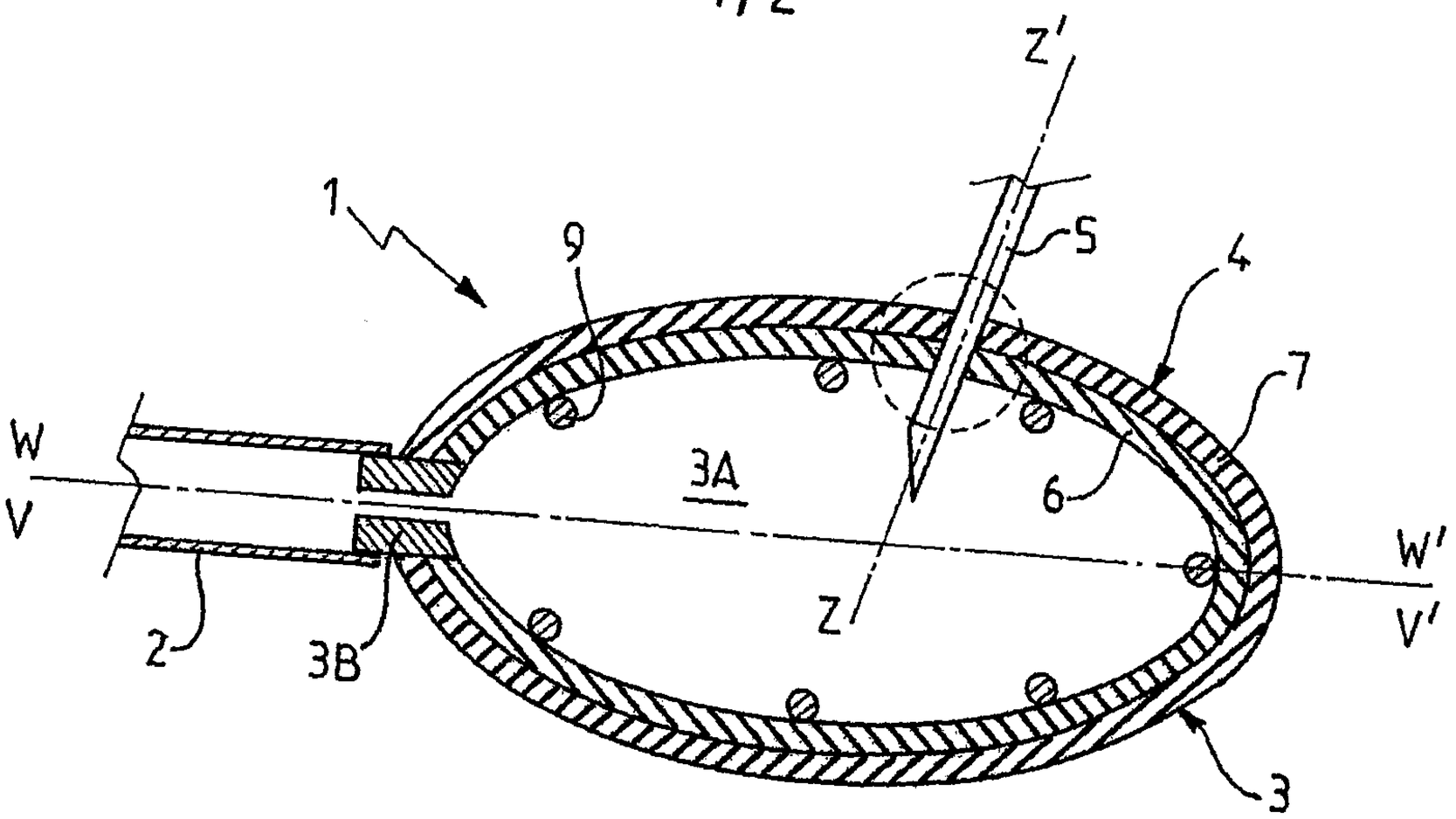


FIG.1

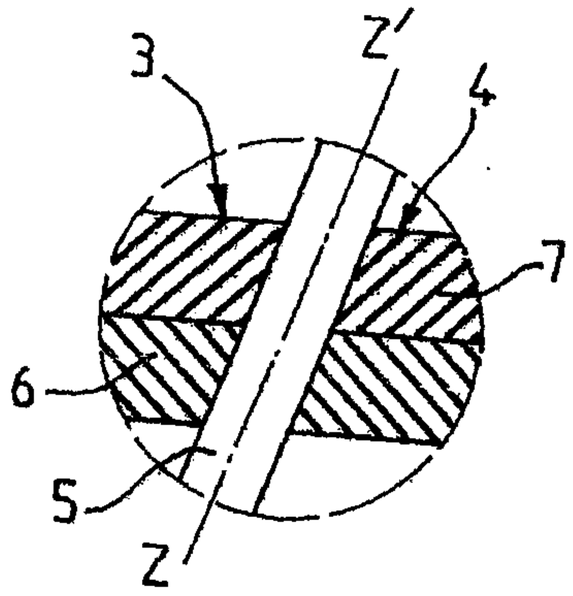


FIG.2

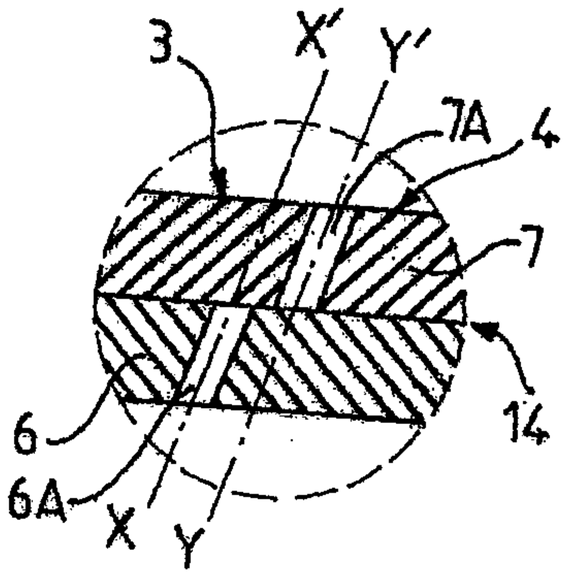


FIG.3

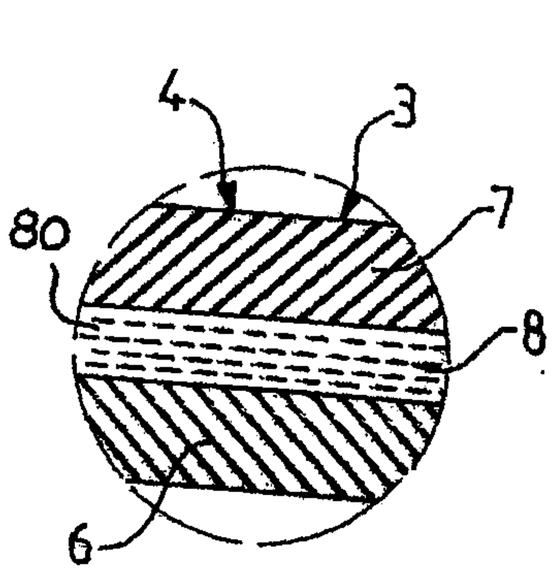


FIG.4

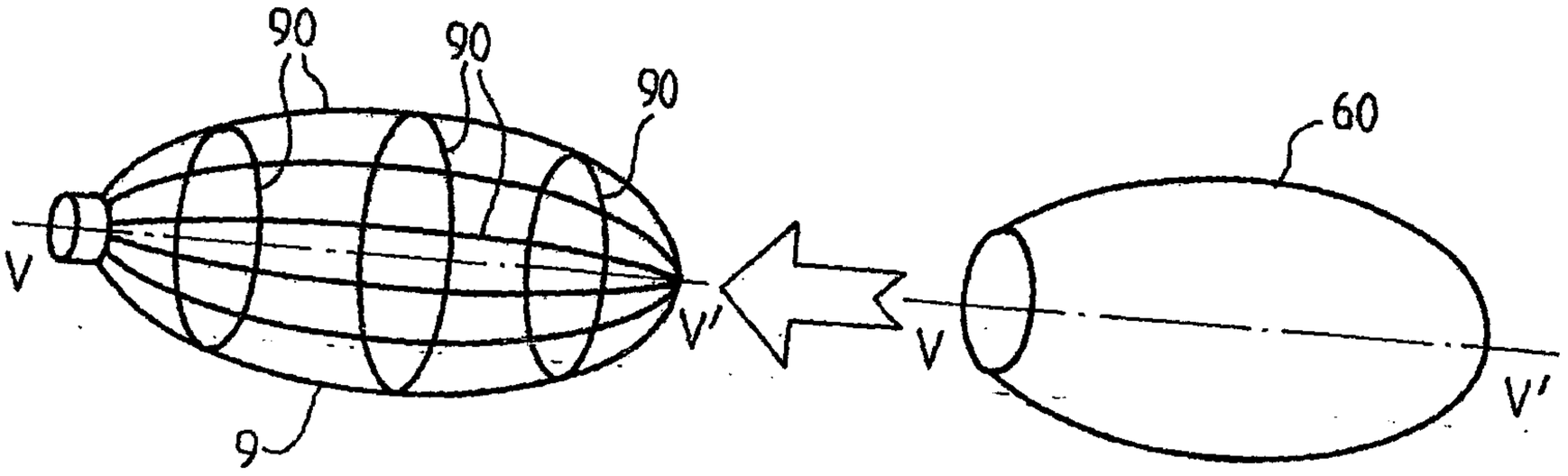


FIG.5

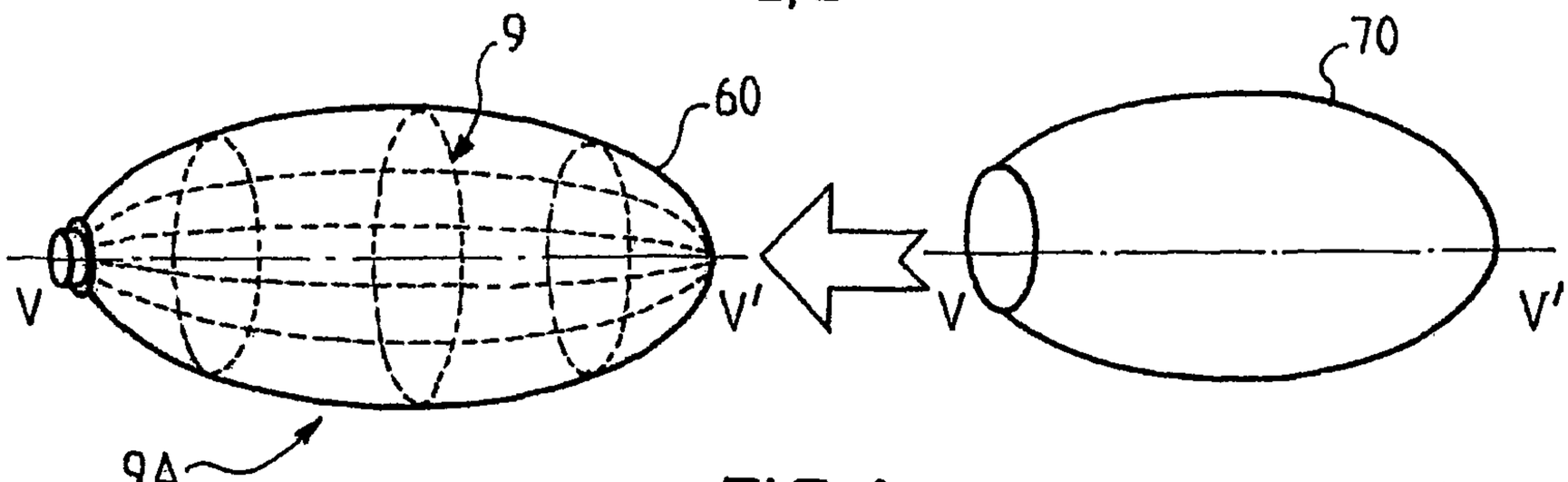


FIG.6

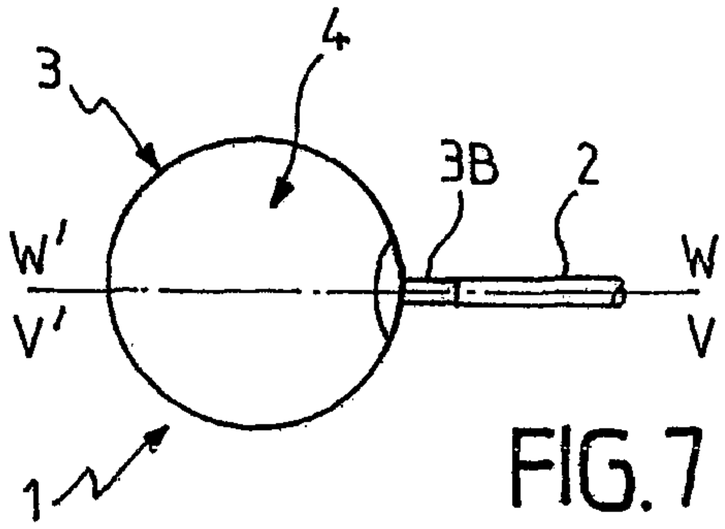


FIG.7

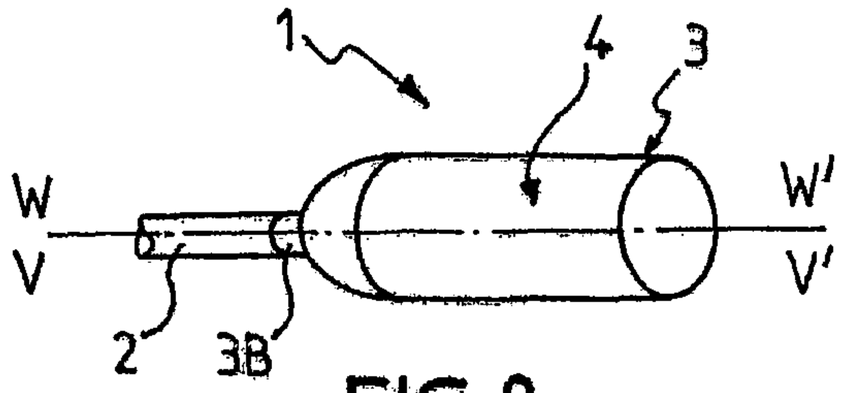


FIG.8

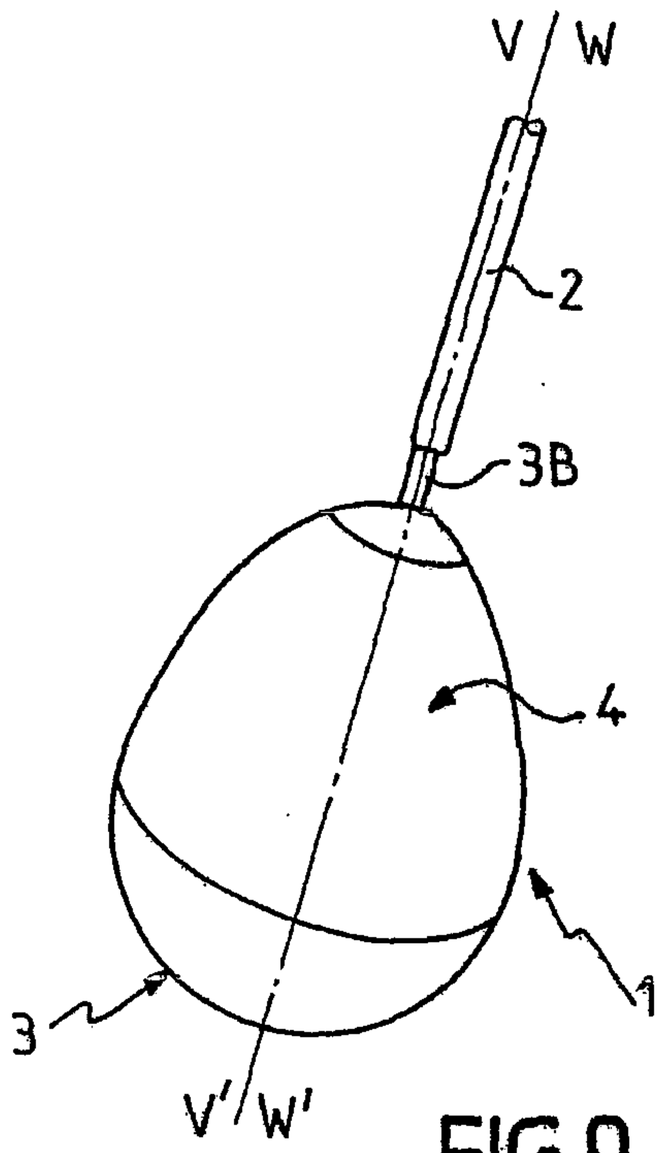


FIG.9

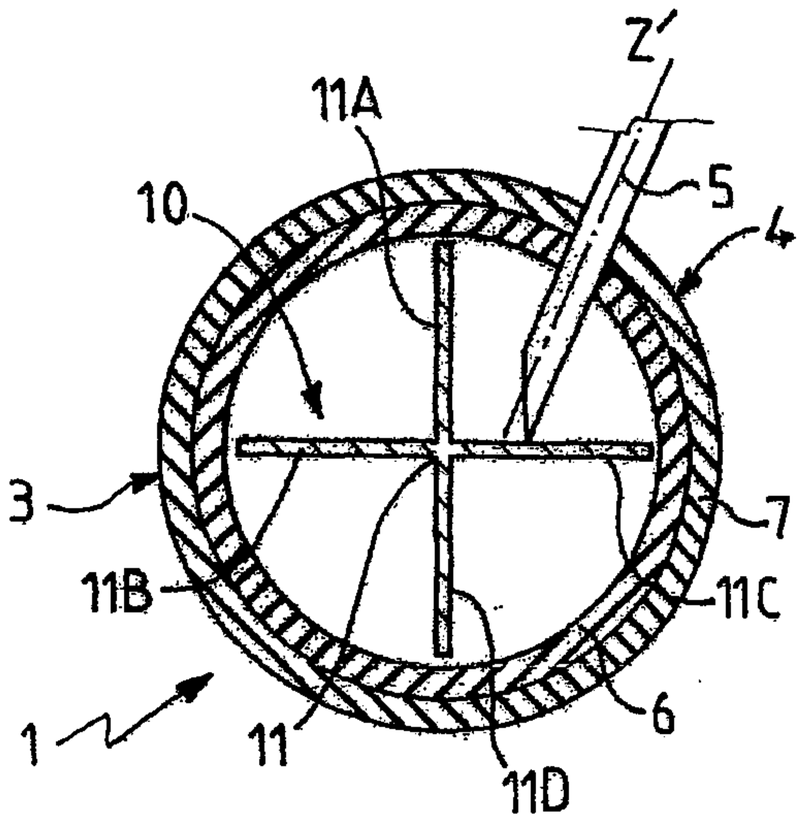


FIG.11

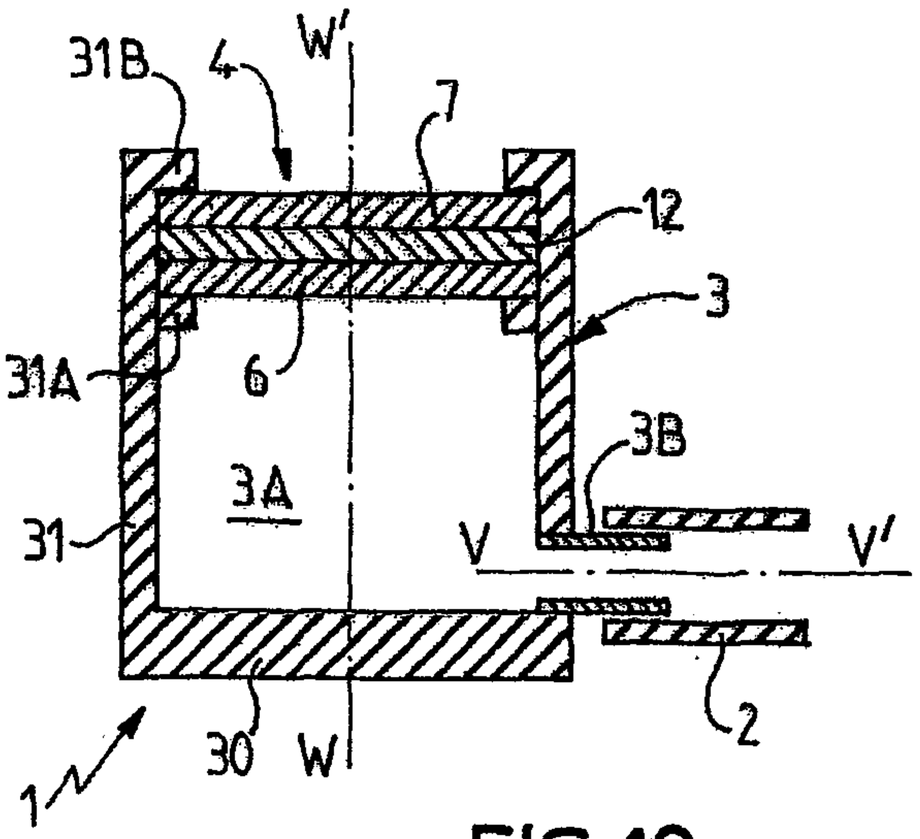
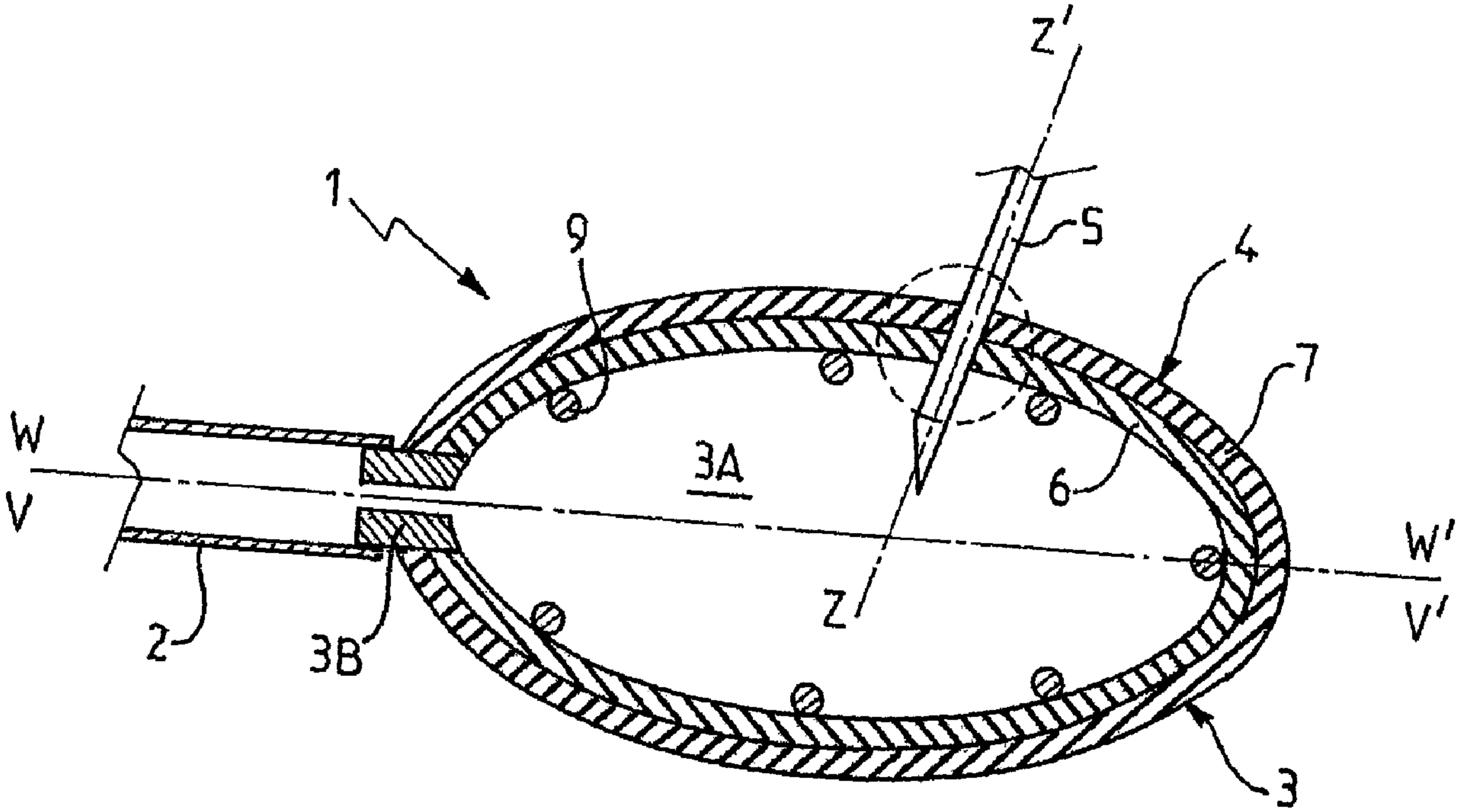


FIG.10


Z'
1
9
S
4
7
W
V
3A
6
W'
V'
Z
2
3B
3