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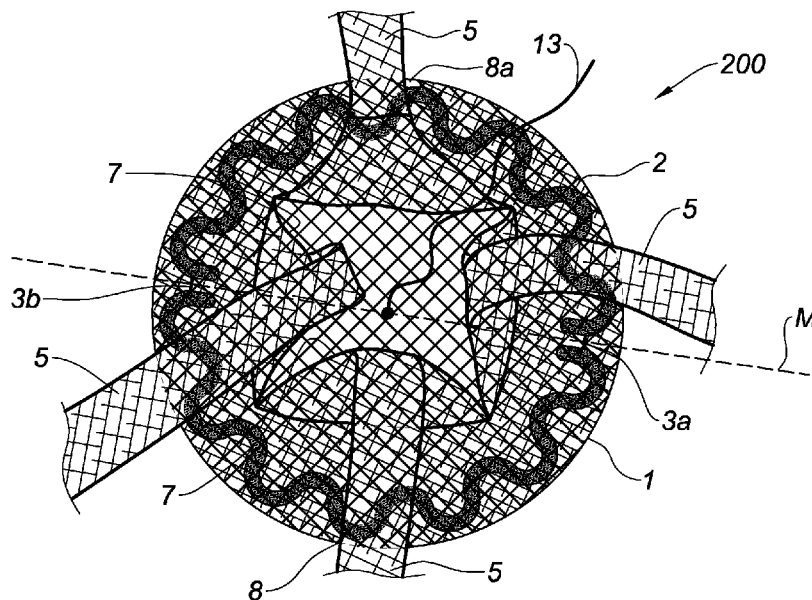


Fig. 8A

(57) Abstract: The present invention relates to a prosthesis (200) comprising: -at least one flexible mesh (1) delimited by a peripheral exterior edge (1a), -at least two tongues (5) extending from one face of the mesh, and -at least one member for reinforcing said mesh, characterized in that said reinforcing member takes the form of a frame (2) fastened to said mesh and substantially adopting the shape of said peripheral exterior edge of the mesh, said frame being set back from said peripheral exterior edge and being provided with two hinge points (3a, 3b), the line passing through said two hinge points also passing through the centre (1b) of the mesh and thus forming a line M for folding the mesh in two.



## Umbilical hernia prosthesis

The present invention provides a prosthesis, for repairing hernias, for example, comprising a mesh and a member for reinforcing the mesh.

5 In humans the abdominal wall consists of fat and muscles interconnected by aponeuroses. A break in continuity may occur at the level of the aponeuroses, allowing part of the peritoneum to pass through and form a sac, known as a hernia, containing either fat or a portion of the intestine. Hernias or ventral ruptures (hernias occurring on a parietal surgical scar) are  
10 manifested by a protrusion on the surface of the skin and are called umbilical or inguinal hernias or ventral ruptures, for example, as a function of their location.

To repair a hernia, surgeons often fit a synthetic mesh prosthesis that replaces or reinforces the weakened anatomical tissue.

However, the efficacy of the prosthesis, and thus minimizing the  
15 risk of relapse, depend to a great degree on the proper fixing of the prosthesis. In particular, before being fixed, the prosthesis must be correctly spread over the abdominal wall that it is intended to reinforce. Prostheses of mesh type, i.e. based on an arrangement of threads forming a textile, are generally flexible, and to introduce them into the hernia they are often folded to reduce their  
20 volume. They therefore tend to form creases on the abdominal wall when they are introduced onto the implantation site. In this respect spreading them out is of primary importance but may prove difficult, in particular in the case of treating an umbilical hernia, which, being smaller than an inguinal hernia, offers little working space and little visibility for manipulation of the prosthesis by the  
25 surgeon.

In the case of umbilical hernias, for example, or when the aim of treatment is to repair trocar holes or preventive, the size of the defect to be treated is small, for example from 1 to 4 cm diameter, and open surgery may be envisaged without widening the defect. However, in this type of surgery, the  
30 surgeon has little working space and little visibility. It would thus be preferable to have a prosthesis that is easy to position, to spread out and to fix, if possible avoiding the necessity for sutures at the periphery of the prosthesis, which is complicated and laborious under such working conditions.

Failure to spread the prosthesis out perfectly against the abdominal  
35 wall leads to the risk of trapping the peritoneal sac and the risk of insertion of a soft organ between the prosthesis and the abdominal wall, which can lead to

the risk of adhesions, pain and intestinal blockage and increase the possibility of relapse. It is therefore essential for the surgeon to be sure that no part of the prosthesis remains folded and that no viscera or any part of the intestines lie between the prosthesis and the abdominal wall. Moreover, incorrect positioning of the sutures or incorrect fixing of the prosthesis risks distortion of the prosthesis and the creation of tensions.

Thus in the case of an umbilical hernia in particular, having a small orifice for introducing the prosthesis, it would be beneficial to have a prosthesis adapted to occupy a small volume in a first configuration in order to facilitate its introduction into the abdominal cavity via said orifice and then to be deployed, spread out and pressed easily against the abdominal wall so that the surgeon is sure of the optimal positioning of the prosthesis and can moreover fix the prosthesis efficaciously without sutures at its periphery, and this, despite the little intrinsic visibility of small size hernias.

Various prostheses that may be folded up and then deployed are available.

Accordingly, it is an object of the present invention to overcome or at least ameliorate one or more of the foregoing disadvantages, or to provide a useful alternative.

The present disclosure relates to a prosthesis that is adapted to be folded up in order to reduce the volume that it occupies at the time of its introduction into a small incision and on the other hand to be spread out and fixed easily so that the surgeon is sure of the perfect spreading of the prosthesis and that it may be fixed efficaciously at a certain distance between the centre of the prosthesis and its periphery without sutures at the periphery of the prosthesis and this, despite the little intrinsic visibility of small size hernias.

The prosthesis disclosed herein also relates to treatment of hernias of the abdominal wall, in particular for treating umbilical hernias where the defect is small.

An aspect of the present invention provides a prosthesis comprising: - at least one flexible mesh delimited by a peripheral exterior edge - at least two tongues extending from one face of the mesh, and - at least one reinforcing member which takes the form of a frame fastened to said mesh and substantially adopting the shape of said peripheral exterior edge of the mesh, said frame being set back from said peripheral exterior edge and being provided with two

hinge points, a folding line passing through said two hinge points also passing through the centre of the mesh for folding the mesh in two.

The reinforcing member or frame may be rigid or have some flexibility. According to an embodiment, the mesh and thus the prosthesis can be folded in two because of the presence of the two hinge points of the frame, regardless of the presence or not of intrinsic elastic properties of the frame.

In the context of the present application the term "mesh" refers to an arrangement of biocompatible threads, for example a knitted, woven or non- woven material, preferably of the openwork kind, i.e. having pores encouraging tissue recolonization. Such a mesh may be bioresorbable, partly bioresorbable or permanent. It is sufficiently flexible to be folded up at the time of its introduction into the abdominal cavity. The mesh may be produced from one layer of textile or from a plurality of layers of textiles. Such meshes are well known to the person skilled in the art. The mesh usable for the invention may be supplied in any shape (rectangular, square, circular, oval, etc.) and then cut to match the shape of the hernia defect. For example, the mesh may have the overall shape of a disc or an oval: in this case the frame also has a circular or oval shape and is preferably in the form of a ring. Alternatively, the mesh may have a globally square or rectangular shape: in this case the frame also has a square or rectangular shape. According to an embodiment, the frame is set back from the exterior peripheral edge of the mesh: thus, whilst adopting the shape of the contour of the mesh, the frame has an exterior perimeter smaller than that of the exterior peripheral edge of the mesh: in other words, the exterior peripheral edge of the mesh extends a certain distance beyond the frame. This distance may be greater than or equal to 1 mm, for example. In other words also, the frame and the exterior peripheral edge of the mesh are of similar geometric shape but the frame shows dimensions which are less than that of the exterior peripheral edge of the mesh.

According to an embodiment and, as will become apparent from the following description, the shape of the frame and its location, set back slightly from the exterior peripheral edge of the mesh, enable the surgeon, when implanting the prosthesis, to fix it to the peritoneum efficaciously without requiring sutures at the periphery of the mesh: the surgeon is able to fix the prosthesis along the interior contour of the frame only, said interior contour defining a stitches fixing line: this avoids the surgeon having to apply stitches to the prosthesis at the exterior peripheral edge of the mesh, which is difficult to reach and hardly visible because of the

small size of the incision. The interior contour of the frame of the prosthesis according to an embodiment, defines a fixing line, or stitching line, located approximately half way between the centre of the mesh and its exterior peripheral edge, along which the surgeon may locate the stitches when he fixes the prosthesis to the abdominal wall. Nevertheless, perfect spreading out of the prosthesis according to at least a preferred embodiment is assured by the presence of the frame which, by adopting the shape of the contour of the exterior peripheral edge, ensures deployment of the prosthesis and pressing thereof onto the abdominal wall.

In one embodiment, the mesh is a knitted fabric: because of the stitches that form it, a knitted fabric makes it possible to obtain openwork faces encouraging cellular recolonization after implantation. The knitted fabric may be a two-dimensional knitted fabric or a three-dimensional knitted fabric.

In the context of the present application, the expression "two-dimensional knitted fabric" means a knitted fabric having two opposite faces linked together by stitches but having no spacers imparting a certain thickness to it: such a knitted fabric may be obtained, for example, by knitting threads on a warp or Raschel knitting machine using two guide bars. Examples of two-dimensional knitted fabrics suitable for the present invention are given in the document W02009/071998.

In the present application, the expression "three-dimensional knitted fabric" means a knitted fabric having two opposite faces linked together by spacers imparting a significant thickness to the knitted fabric, said spacers consisting of connecting threads additional to the threads forming the two faces of the knitted fabric. Such a knitted fabric may be obtained, for example, using a double-bed Raschel knitting machine or warp knitting machine with a plurality of guide bars. Examples of knitting three-dimensional knitted fabrics suitable for the present invention are given in the documents W099/05990, W02009/031035, W02009/071998.

In one embodiment, said frame is set back from the exterior peripheral edge and is of serpentine shape, forming undulations. For example, said frame is in the form of a flat ribbon forming undulations substantially in the plane of said mesh. As will become apparent from the description given hereinafter, this configuration of the frame makes it possible, when fixing the prosthesis to the biological tissue, to execute a suture in the prosthesis at a given location without deforming the prosthesis as a whole during this operation; deformation of the prosthesis

caused by the suture at the given location is smoothed out by the undulating frame. Thus the frame and therefore the rest of the prosthesis remain correctly positioned, and in particular remain pressed against the abdominal wall, during the fixing of the prosthesis. In addition, the frame preferably possesses a certain rigidity along its section.

5 In one embodiment, said reinforcing member is produced in bioresorbable material. Thus the reinforcing member fulfils its role of stiffening the prosthesis during positioning and implantation of the prosthesis and is then degraded progressively once the mesh is recolonized by the surrounding cells.

0 The bioresorbable material may be chosen, for example, from polylactic acid (PLA), polycaprolactone (PCL), polydioxanone (PDO), trimethylene carbonate (TMC), polyvinyl alcohol (PVA), polyhydroxyalkanoate (PHA), oxidized cellulose, polyglycol acid (PGA), copolymers of these materials and mixtures thereof.

5 Alternatively, the reinforcing member may be produced in a non- bioresorbable material chosen from polypropylene, a polyester such as polyethylene terephthalate, polyamide, silicone, polyetheretherketone (PEEK), polyaryletheretherketone (PAEK) and mixtures thereof.

In another embodiment, said reinforcing member is produced from a combination of bioresorbable material and non-bioresorbable material.

20 In one embodiment, said tongues have a globally rectangular shape and are provided at one of their ends with a widened part by which they are fixed to said mesh. As will become apparent from the description given hereinafter, the tongues are useful to the surgeon by facilitating positioning of the prosthesis at the centre of the defect to be treated and for fixing the prosthesis to the biological tissue.

25 In one embodiment, said tongues are textile tongues. The textile of the tongues may be identical to that of the mesh or different. The tongues may be made of bioresorbable material or not. A suitable bioresorbable material for the manufacturing of the tongues may be selected from bioresorbable materials mentioned above for the reinforcing member.

In one embodiment, the widened part being separate from the rest of the tongue, said widened part is produced in gripping textile and can thus be attached to and/or detached from the rest of the tongue at will. Examples of production of gripping textile are described in the document W00181667.

5 For example, the widened part of the tongues may be sewn to said mesh. The widened part enables better fixing of the tongues to the mesh. In one embodiment, the widened part of the tongues is fixed to the mesh by means of the reinforcing member.

In one embodiment, said two tongues are fixed on either side of said folding line, preferably at two places symmetrical about this folding line.

0 In one embodiment, said mesh has the shape of a disc, said frame being substantially in the form of a circular ring, and said tongues are fixed to two diametrically opposed places on said ring, said two places being spaced by 90° from each of said two hinge points. The face of the mesh including said two tongues may be provided with two additional tongues fixed to the mesh at the locations of the two hinge points of the ring.

5 In one embodiment, at least a portion of the tongues is of a colour different from that of the mesh: for example, the widened parts of the tongues may be of a colour different from that of the mesh. Indeed, the colour difference between the widened parts of the tongues, or the whole tongues, and the mesh is particularly preferable in view of the little visibility offered by the small size of the working area : this colour difference allows defining a line, said line  
20 pointing out to the surgeon where to complete the stitches for fixing the prosthesis to the abdominal wall.

In embodiments, said mesh being disc-shaped and said frame being substantially in the form of a circular ring, said prosthesis comprises four of said tongues, the widened parts of which being of a colour different from that of the mesh, said four widened parts being  
25 distributed along an interior contour of said ring, symmetrically with respect to said folding line M, two of said widened parts on one side of said folding line M, the other two of said widened parts on the other side of said folding line M.



In embodiments, all four widened parts are under the form of isosceles triangles of textile, each triangle being fixed to said mesh via its base, all four triangles showing identical elongation and tensile strength properties in the centripetal direction.

For example, each isosceles triangle is fixed to the mesh via its base by means of the ring, the rectangular part of the tongue being attached to the vertex angle of the isosceles triangle. Because of the four isosceles triangles of textile having the same mechanical properties in the centripetal direction, when the surgeon pulls on the rectangular parts of the four tongues at the time he puts the prosthesis in place and fixes it to the abdominal wall, all widened parts of the tongues react similarly and the traction exerted by the surgeon on the whole prosthesis via the four tongues is regularly distributed. The prosthesis according to at least a preferred embodiment may, therefore be properly positioned. In addition, because the four isosceles triangles of textile have a colour different from that of the mesh, the surgeon readily identifies the stitching line as defined above and the step of fixing the prosthesis to the abdominal wall is facilitated. As will appear from the description below, the method of manufacturing a prosthesis with four widened parts under the form of four isosceles triangle of textile having identical mechanical properties is simple and easy.

In one embodiment, the free ends of the tongues are joined together by a centring thread. Such a configuration enables the surgeon to use the centring thread to position and fix the prosthesis particularly easily and effectively when implanting the prosthesis, as will become apparent from the description given below.

In one embodiment, the face of the mesh opposite that including said tongues is covered with a non-adherent coating.

Such a coating makes it possible in particular to avoid the formation of unwanted severe post-operative fibrous adhesions.

In the context of the present application the expression "non-adherent" refers to a non-porous, smooth, biocompatible coating or material offering no space for cellular recolonization and preferably encouraging the birth of a peritoneum.

Preferred embodiments of the invention will be described hereinafter, by way of examples only, with reference to the accompanying drawings.

Figure 1 is a representation in section of a median abdominal hernia or ventral rupture,

Figure 2 is a simplified view of the hernia from Figure 1 after the surgeon has made an abdominal incision and removed the hernia sac,

Figure 3 is a top view of one embodiment of a mesh for a prosthesis of the invention,

Figure 4 is a top view of a reinforcing member for the prosthesis of the invention,

Figure 5 is a top view of a tongue of the prosthesis of the invention,

Figure 6 is a top view of the mesh and the reinforcing member of

the prosthesis of the invention,

Figure 7A is a top view of the mesh, the reinforcing member and a tongue of the prosthesis of the invention,

5 Figure 7B is a view of the prosthesis from Figure 7A when a second tongue has been fitted,

Figure 8A is a top view of the prosthesis of the invention,

Figure 8B is a perspective view of a variant of the prosthesis of the invention,

10 Figure 9 is a simplified sectional view of the introduction of the prosthesis from Figure 8B into the hernia defect,

Figure 10A is a simplified sectional view of the positioning of the prosthesis from Figure 8B after deployment thereof at the implantation site,

Figure 10B is a simplified sectional view of the fixing of the prosthesis from Figure 8B,

15 Figure 11 is a view in section of the prosthesis from Figure 8B when fixed to the biological tissues just before closure of the abdominal incision by the surgeon,

Figure 12 is a top view of an embodiment of the prosthesis of the invention with two tongues,

20 Figure 13 is a simplified sectional view of the placement of a prosthesis of the invention using the tongues from Figure 12,

Figure 14-17 are top views showing the successive steps of a method for manufacturing a prosthesis of the invention comprising four widened parts of textile having identical mechanical properties.

25 Figure 1 represents a hernia defect 100 of the abdominal wall 101 that is characterized by a break in the continuity of the aponeurosis 102 surrounding the straight muscles 103 and a passage through the peritoneum 104 forming a sac, the hernia sac 105, that contains either fat (epiploon) or part of the viscera 106, and which then presses on the fatty tissues 107 and is flush  
30 with the skin 108. One treatment of a hernia defect 100 entails replacing and retaining the viscera 106 in the abdominal cavity 109.

Figure 2 shows the hernia defect 100 from Figure 1 after the surgeon has made an incision in the skin 108, the abdominal wall 101 and the peritoneum 104 and has reduced the hernia sac. The viscera are not shown in  
35 Figure 2: they have been pushed back into the abdominal cavity 109. The surgeon must now introduce into the abdominal cavity 109, via the incision 110

that has been made, a prosthesis for reinforcing the abdominal wall, before closing the incision 110 by means of sutures, for example. In the case of an umbilical hernia, the size of the incision 110 is particularly small, for example of the order of 1 to 4 cm diameter.

5                Figure 3 represents a mesh 1 in the form of a disc usable with the reinforcing member from Figure 4 and tongues such as that from Figure 5 to produce a prosthesis of the invention.

              The mesh 1 is made from a knitted, woven or non-woven arrangement of biocompatible threads. It may be bioresorbable, partly  
10                bioresorbable or permanent. The mesh is generally openwork, incorporating pores for better tissue integration. This mesh 1 is sufficiently flexible to be folded when the prosthesis is introduced into the abdominal cavity 109 via the incision 110. However, the mesh is generally a textile having no elasticity enabling it to return to a spread out configuration of its own accord after it has  
15                been folded up. The mesh 1 may be produced from a textile layer or a plurality of textile layers. The textile may be a two-dimensional or three-dimensional knitted fabric. Such meshes are well known to the person skilled in the art and are not described in more detail here. The mesh may be supplied in the form of a strip that is cut to the dimensions of the defect to be treated. In the example  
20                represented, the mesh 1 has the shape of a disc adapted to the shape of the incision 110 at the hernia defect 100 and delimited by an exterior peripheral edge 1a. In other embodiments, the mesh may be of oval shape. Alternatively, the mesh may be of rectangular or square shape.

              Figure 4 represents a reinforcing member of a prosthesis of the  
25                invention, suitable for the shape of the mesh 1 from Figure 3: as is apparent from Figure 4 and Figure 6, the reinforcing member takes the form of a frame 2 substantially adopting the shape of the exterior peripheral edge 1a of the mesh 1. Thus the overall shape of the frame 2 is a circular ring. The frame 2 is provided with two hinge points 3a and 3b that are diametrically opposite in the  
30                example shown. The two hinge points (3a, 3b) make it possible to fold the frame 2, for example when force is applied by the surgeon, resulting in two globally identical parts. The hinge points (3a, 3b) preferably do not have any elasticity of their own: thus, once folded in two, the frame 2 can be unfolded only by the action of an external force, for example exerted by the surgeon.

35                The frame 2 thus consists of two parts, namely two semicircles 2a and 2b, connected together by two hinge points (3a, 3b). As seen in Figure 4,

the respective ends (2c; 2d) of the semicircles 2a and 2b are blunted or rounded to prevent trauma when implanting the prosthesis. In the example shown, the two semicircles 2a and 2b are symmetrical: the two hinge points (3a; 3b) define a median line M passing through the centre of the circle delimited by the frame and also through the centre of the mesh 1 when the frame 2 is fixed to the mesh 1, as shown in Figure 6. Thus the mesh 1 may be folded in two even when fitted with the frame 2: consequently, as will become apparent in the remainder of the description, the prosthesis may be folded. Similarly, given the configuration of the frame 2 in two parts and the absence of any elasticity of the frame 2 and its hinge points (3a, 3b), the prosthesis is able to adopt only two configurations: either a flat and spread out configuration or a folded in two configuration. As explained later, the fact that the prosthesis can adopt only two configurations facilitates the task of the surgeon, who can immediately determine if the prosthesis is in its spread out configuration or not.

As seen in Figures 4 and 6, the frame 2 is an undulating ring set back from the exterior peripheral edge 1a, consisting of undulations 4. Referring to Figure 6 in particular, the exterior peripheral edge 1a of the mesh extends some distance beyond the exterior contour of the frame 2: this distance may be greater than or equal to 1 mm, for example. As will become apparent from the description given hereinafter, the location of the frame 2, slightly set back from the exterior peripheral edge 1a, facilitates efficacious fixing of the prosthesis to the abdominal wall, in particular in an area located more or less half way between the centre and the edge of the mesh.

The undulations 4 of the frame 2 may be regular or not. In particular, in the example shown, the frame 2 is in the form of a flat ribbon of material forming undulations 4 in the plane of the frame 2, which is substantially the plane of the prosthesis. As will become apparent in the remainder of the description, such a shape imparts to the frame 2 great flexibility in the plane of the frame 2 and thus in the plane of the prosthesis: it is thus possible to suture part of the prosthesis at a given place, without rocking or deforming the prosthesis as a whole: the deformation created at the location of the suture is smoothed out by the undulations 4 of the frame 2 over the whole of the periphery of the prosthesis. In addition, the frame 2 shows a rigidity along its section, so that it neither deforms radially in the outward nor in the inward directions.

Materials suitable for producing the reinforcing member of the

prosthesis of the invention may be any biocompatible materials having some rigidity so as to respond to the expectations disclosed above.

The frame 2 can thus be produced in any biocompatible material, bioresorbable or not. In a preferred embodiment, it is made in bioresorbable material. In the present application, the term "bioresorbable" refers to the characteristic whereby a material is absorbed by biological tissues and disappears *in vivo* after a given period, which may vary from one day to several months, for example, depending on the chemical nature of the material.

Bioresorbable materials suitable for the fabrication of the reinforcing member of the prosthesis of the present invention include polylactic acid (PLA), polycaprolactone (PCL), polydioxanone (PDO), trimethylene carbonate (TMC), polyvinyl alcohol (PVA), polyhydroxyalkanoate (PHA), oxidized cellulose, polyglycolic acid (PGA), copolymers of these materials and mixtures thereof. Bioresorbable materials suitable for the fabrication of the reinforcing member of the prosthesis of the invention include polyester (glycolid, dioxanone, trimethylene carbonate) available from the company Covidien under the trade name "BIOSYN®" and polyester (glycolid, caprolactone, trimethylene carbonate, lactid) available commercially from the company Covidien under the trade name "CAPROSYN®".

Non-bioresorbable materials suitable for the fabrication of the reinforcing member of the prosthesis of the present invention include polypropylene, polyesters such as polyethylene terephthalate, polyamide, silicone, polyetheretherketone (PEEK), polyaryletheretherketone (PAEK) and mixtures thereof.

Each part of the reinforcing member of the prosthesis of the invention may be made in one piece, for example, by injection moulding one or more biocompatible thermoplastic or thermosetting materials. The hinge points (3a, 3b) of the frame 2 may be produced in the same material as the rest of the frame: these hinge points (3a, 3b) take the form for example of very thin bridges of material in order to enable folding of the frame 2 without causing separation of the two parts joined together by these bridges.

Figure 5 shows a tongue 5 suitable for the prosthesis of the invention. As may be seen in this figure, the tongue 5 has a globally rectangular part 6 and a widened part 7 situated at one end 6a of the rectangular part 6, said end 6a forming a junction between the rectangular part 6 and the widened part 7. In this figure, the widened part 7 has a trapezoidal overall shape with a

circular arc base 7a: as may be seen in Figures 7A and 7B, the widened part 7 of each tongue 5 is intended to be fixed to the mesh 1, for example by means of the frame 2. Alternatively or in addition, the widened part 7 of the tongue 5 may be sewn to the mesh along a seam 7b as shown in Figure 7A.

5           The free end 6b of the rectangular part 6 may be joined to the free ends of the other tongues 5, as shown in Figure 8B. The free ends 6b of the tongues may be joined during fabrication of the prosthesis or at the time of implantation by the surgeon. Thus the length of the rectangular part 6 must be sufficient to enable joining of the tongues 5: nevertheless, this length must not  
10 be too great in order not to impede the surgeon at the time of implanting the prosthesis. The length of the rectangular part 6 is preferably from 2 to 6 cm and more preferably from 2 to 4 cm.

          In the embodiment shown on Figure 5, the tongue 5 is made in one piece. In other embodiments described below with respect to Figures 14-17,  
15 the widened part and the rectangular part may be two separate parts that are assembled before use. In such a case, the two parts may be in different materials.

          The tongue 5 may be produced in any biocompatible material imparting to it the flexibility necessary for it to be picked up by the surgeon  
20 during fitting of the prosthesis, as described hereinafter. The tongues 5 are intended to assist the surgeon to position the prosthesis relative to the hernia and then to fix it to the abdominal wall.

          For example, the tongue 5 is in textile. This textile may be identical to that forming the mesh 1 or different. In an embodiment in which the widened  
25 part and the rectangular part are two initially separate parts, the widened part for example may consist of a gripping textile as described in WO0181667 and the rectangular part may consist of an openwork textile stuck to the widened part.

          The tongues may be realized in a bioresorbable material, for  
30 example such as that described above for the reinforcing member.

          Figure 8A shows a prosthesis 200 of the invention made with the mesh 1 from Figure 3, the frame 2 from Figure 4 and four tongues 5 from Figure 5.

          In an embodiment of the invention that is not shown, the prosthesis  
35 of the invention has only two tongues: in such a case, the two tongues are preferably fixed on either side of the folding line M, for example by means of

the reinforcing member.

In the embodiment shown in Figure 8A, the four tongues 5 are arranged symmetrically around the ring formed by the frame 2 in order to balance each other. In particular, two of the tongues 5 are fixed to two diametrically opposite places 8 and 8a of the frame 2, said two places being each spaced by 90° from the hinge points 3a and 3b. Two other tongues 5 are fixed at the locations of the two hinge points 3a and 3b. Each tongue 5 is fixed to the mesh 1 by its widened part 7, the circular arc parts of the widened parts of the tongues 5 being adjacent in pairs. The centre 1b of the mesh 1 is moreover provided with a centring thread 13. This centring thread is intended to be grasped by the surgeon when fitting the prosthesis 200 on the implantation site. The centring thread 13 is long enough to enable the surgeon to manipulate it outside the body of the patient with the prosthesis 200 inside the body of the patient. The presence of the four tongues 5, regularly distributed as described above, and the centring thread 13 enables the surgeon to balance the tension between the various tongues at the time of positioning the prosthesis and to centre the latter prosthesis better relative to the defect to be closed.

In one embodiment of the prosthesis 200 the reinforcing member, namely the frame 2 in the example shown, is welded directly to the mesh 1 and to the circular arc parts 7a of the four tongues 5. Thus the frame 2 is fastened both to the mesh 1 and to the widened parts 7 of the tongues 5. The prosthesis 200 is thus substantially contained in a plane comprising the mesh 1, the frame 2 and the widened parts 7 of the tongues 5.

In another embodiment of the invention, shown in Figure 8B, the centring thread 13 is not fixed to the centre of the mesh 1 but joins the free ends 6b of the four tongues 5. This centring thread 13 may then be placed by the surgeon before implanting the prosthesis 200. In this embodiment, the centring thread 13 may pass through the tongues 5 or simply surround them to hold them together without passing through them.

In the Figure 8B embodiment, the face of the mesh 1 opposite that including the tongues 5 is covered by a non-adherent coating 201. Such a non-adherent coating makes it possible to avoid in particular the formation of unwanted severe post-operative fibrous adhesions; once the prosthesis 200 has been implanted, the face of the prosthesis 200 covered by the non-adherent coating 201 faces the abdominal cavity 109.

The non-adherent coating or material is chosen from bioresorbable



materials, non-bioresorbable materials and mixtures thereof. The non-bioresorbable non-adherent materials may be chosen from polytetrafluoroethylene, polyethylene glycol, polysiloxane, polyurethane, and mixtures thereof.

5            Said non-adherent coating or material is preferably bioresorbable: bioresorbable materials suitable for said non-adherent coating may be chosen from collagen, oxidized cellulose, polyacrylate, trimethylene carbonate, caprolactone, dioxanone, glycolic acid, lactic acid, glycolide, lactide, polysaccharide, for example chitosan, polyglucuronic acid, hyaluronic acid,  
10 dextran and mixtures thereof.

          The non-adherent coating makes it possible to protect the mesh 1 of the prosthesis 200 at least during the initial scar formation phase, i.e. the mesh 1 is not exposed to inflammatory cells, such as granulocytes, monocytes, macrophages or the giant multinucleated cells generally activated by surgery.  
15 At least during the initial scar formation phase, the duration of which may vary from about 5 days to about 10 days, only the non-adherent coating is accessible to the various factors such as proteins, enzymes, cytokines or inflammatory cells.

          If the non-adherent coating consists of non-resorbable materials, it  
20 thus protects the mesh 1 before and after implantation and throughout the duration of implantation of the prosthesis 200.

          Moreover, thanks to the non-adherent coating, surrounding fragile tissues, such as the hollow viscera, for example, are protected, in particular from unwanted severe post-operative fibrous adhesion.

25            If the non-adherent material includes a bioresorbable material, it is preferable to choose a bioresorbable material that is not resorbed in less than a few days in order for the non-adherent coating to be able to fulfil its function of protecting the intestine and hollow organs during the days following surgery until cellular rehabilitation of the prosthesis takes over protecting these fragile  
30 organs.

          Because of its two-part reinforcing member, namely the frame 2 consisting of the two semicircles 2a and 2b in the example shown, connected together by hinge points 3a, 3b, the prosthesis 200 of the invention may adopt a folded configuration after the surgeon folds it along the folding line M. Thus to  
35 implant the prosthesis 200 the surgeon folds it in two so that it occupies a smaller volume, which facilitates introduction of the prosthesis into the hernia

defect 100 (see Figure 2) by the surgeon.

The mesh 1 and the non-adherent coating 201 are sufficiently flexible to follow successive deformations of the prosthesis 200 as the latter is introduced to the implantation site.

5           Figures 14-17 describe various steps of a method for manufacturing an embodiment of a prosthesis 210 of the invention made with the mesh 1 of Figure 3, the frame 2 of Figure 4 and four widened parts 207, made separately from the rectangular parts of the tongues. For clarity's sake, the rectangular parts of the tongues are not shown on Figures 14-17 : these  
10 rectangular parts are similar to the rectangular part 6 of tongue 5 of Figure 5 and may be either integrate with the widened parts 217 or else attached to said widened parts 217 by any fixation means such as sewing, welding, gluing or by means of a gripping textile.

As will appear from the description below, the four widened parts  
15 217 of prosthesis 210 are arranged symmetrically along the interior contour of the ring formed by the frame 2, and they all have the same mechanical properties.

The manufacturing process of such embodiments will now be described with reference to Figures 14-17.

20           With reference to Figure 14, is shown a textile 20 for forming the widened parts 217 of tongues of the prosthesis 210 (see Figure 17). On the example shown, the textile 20 has the shape of a square, the length of one side of the square being greater than the greater diameter of the intended resulting prosthesis 210. This textile 20 may be identical to that forming the mesh 1 or  
25 different. The textile 20 is for example produced on a knitting machine and has a warp direction  $W_a$  and a weft direction  $W_e$ , as shown on this Figure 14. The textile 20 may have different mechanical properties, such as elongation and tensile strength, along its warp direction  $W_a$  and along its weft direction  $W_e$ .

Preferably, the textile 20 has a colour different from that of the  
30 mesh 1.

In order to proceed with the manufacturing of the four widened parts 217, a cutting 21 having the shape of a cross with two perpendicular branches (22, 23) is completed on textile 20, with one branch 22 of the cross parallel to the warp direction  $W_a$  and the other branch 23 of the cross parallel  
35 to the weft direction  $W_e$ , as shown on Figure 15. The branches of the cross may be of identical lengths or not. On the example shown on Figure 15, the

length of the branch 22 parallel to the warp direction  $W_a$  is smaller than the length of the branch 23 parallel to the weft direction. In addition, on this example and as will appear from Figure 16, the length of the branch 22 parallel to the warp direction  $W_a$  is smaller than the diameter of the internal perimeter of the frame 2, whereas the length of the branch 23 parallel to the weft direction is greater than the diameter of the outer perimeter of the frame 2.

In a further step, the textile 20 is laid upon a piece of mesh 1, for example of similar square shape and dimensions as the textile 20, and the frame 2 of Figure 4 is then welded to both the mesh 1 and the textile 20.

As shown on Figure 16, the frame 2 is welded on mesh 1 and textile 20 so that the greater branch 23 of the cutting 21 is applied on the folding line M defined by the frame 2 (see Figure 4) and extends beyond the hinge points (3a, 3b) of the frame 2, whereas the smaller branch 22 of the cutting 21 does not reach the frame 2. Such an embodiment allows a better efficiency of the frame 2, which may not be damaged by residual filaments coming from the cutting of branch 22 when said frame 2 is welded on both the mesh 1 and the textile 20.

Once the frame 2 is welded, the disc-shape prosthesis 210 may be manufactured by cutting the mesh 1 and textile 20 in excess beyond the outer peripheral border of the frame 2, as shown on Figure 17. As appears from this Figure, the frame 2 forms together with the cross-shaped cutting 21 four isosceles triangles 24, more or less fixed to the frame 2 by their respective base 24a and free at their vertex angle 24b. These four isosceles triangles 24 of textile 20 form the widened parts 217 of the tongues (not shown) of the prosthesis 210.

As mentioned above, a rectangular part such as rectangular part 6 of tongue 5 of figure 5 may then be attached to the free vertex angle 24b of each triangle 24 by any fixation means such as sewing, welding, gluing or by means of a gripping textile, in line with the direction defined by the altitude 24c drawn from the vertex angle 24b of each triangle 24.

Because of the specific cross-shaped cutting 21, with one branch parallel to the warp direction  $W_a$  and the other branch parallel to the weft direction  $W_e$ , all four isosceles triangles 24 of textile 20 are identical and they all show the same mechanical properties, such as elongation properties and tensile strength properties, each in the direction of its altitude 24c corresponding to the centripetal direction of the disc-shape prosthesis 210,

regardless from the fact that the initial elongation and tensile strength properties of the textile 20 in its warp direction  $W_a$  were identical or not to its initial elongation and tensile strength properties in the weft direction  $W_e$ .

Indeed, because of the location of the cutting 21 with respect to the  
5 frame 2 during the welding step, the altitude direction or centripetal direction for each triangle 24 forms an angle of  $45^\circ$  with respect to both warp and weft directions of the initial textile 20.

As a consequence, all four widened parts 217 show the same  
mechanical properties, in particular elongation properties and tensile strength  
10 properties, in the direction corresponding to the direction of the altitude 24c of each triangle 24, in other words in the direction of the rectangular part of the tongue (not shown) corresponding to the direction of the traction exerted by the surgeon when he puts the prosthesis in place and fixes it to the abdominal wall.

As a consequence, when the surgeon pulls on the rectangular parts  
15 of the four tongues at the time he puts the prosthesis 210 in place and fixes it to the abdominal wall, all widened parts 217 of the tongues react similarly and the traction exerted by the surgeon on the whole prosthesis 210 via the four tongues is equally distributed. The prosthesis 210 is therefore properly positioned. In addition, because the four isosceles triangles 24 of textile 20  
20 have a colour different from that of the mesh 1, the surgeon readily identifies the stitching line as defined above. The step of fixing the prosthesis 210 to the abdominal wall is therefore facilitated.

The method of manufacturing the prosthesis 210 described above  
is very simple and allows starting from a single piece of textile 20 for  
25 manufacturing the four widened parts 217.

Alternatively, the prosthesis 210 may be manufactured by preparing  
initially four separate triangles 24 of textile 20 and welding each triangle 24 to  
the mesh 1 via the frame 2, or alternatively by preparing two pieces of semi-  
discs of textile 20, completing a perpendicular cutting on each semi-disc and  
30 welding the two cut semi-discs to the mesh via the frame 2.

Like the prosthesis 200 of figures 1-13, the prosthesis 210 of Figure  
17 may be provided with a centring thread 13 and may be coated on the face of  
the mesh 1 opposite that including the widened parts 217 with a non-adherent  
coating 201.

35 The fitting of a prosthesis of the invention, for example the prosthesis 200 from Figure 8B, is described next with reference to Figures 9 to

11. Although not described, the fitting of the prosthesis 210 of Figure 17 may be completed in the same manner as that described hereinafter for prosthesis 200 of Figure 8B.

After making the incision 110 described with reference to Figure 2, the surgeon grasps the prosthesis 200 from Figure 8B, covered with a non-adherent coating 201 on the face of the mesh 1 opposite that including the tongues 5, and applies force to the prosthesis 200 with his fingers to fold it along the folding line M. Because of the presence of the two hinge points 3a and 3b, this operation is without difficulty and totally independent of the elastic or non-elastic nature of the frame 2. In the embodiment shown, the prosthesis 200 being a disc, it is folded along one of its diameters, resulting in two identical parts. In this folded configuration, the prosthesis 200 occupies a small volume and the surgeon may easily introduce it into the abdominal cavity 109, as shown in Figure 9, while holding the centring thread 13 outside the body of the patient. For clarity, the fingers of the surgeon are not represented in Figures 9 to 11.

Once the prosthesis 200 is in the abdominal cavity 109, the surgeon releases the pressure on it. It is the surgeon who manually deploys the prosthesis 200 in a perfectly tensioned and spread out configuration. Thus, the prosthesis 200 being able to adopt only two positions, namely folded in two or spread out, the surgeon is certain that the prosthesis is perfectly spread out from the moment of unfolding the prosthesis 200.

In the next step, as shown in Figure 10A, the surgeon uses the centring thread 13 both to centre the prosthesis 200 relative to the incision 110 and to press the prosthesis 200 against the abdominal wall (101, 104). To this end, the surgeon pulls the centring thread 13 toward the exterior of the body of the patient. Thus the prosthesis 200 is spread perfectly and there is no risk of the viscera being disposed between the widened parts 7 of the tongues 5 and the abdominal wall (101, 104).

Once the prosthesis 200 is correctly positioned relative to the hernia defect, the surgeon withdraws the centring thread 13, thereby releasing the free ends 6b of the tongues 5, as shown in Figure 10B.

In doing this, the surgeon raises a part of the edge of the hernia and thus uncovers a central area 12 in the vicinity of the prosthesis 200, delimited overall by the widened parts 7 of the tongues 5, which area the surgeon may easily view and in which the surgeon is able to work easily. In one

embodiment, the widened parts 7 of the tongues 5 or the tongues 5 as a whole may be a different colour than the mesh 1, in order to facilitate viewing of the central working area 12 by the surgeon. Indeed, the colour difference between the widened parts 7 of the tongues, or the whole tongues 5, and the mesh 1 defines a line, said line pointing out to the surgeon where to complete the stitches for fixing the prosthesis 200 to the abdominal wall. This fixing line, or stitching line, globally corresponds to the interior contour of the frame 2.

In a following step, as shown in Figure 10B, the surgeon proceeds to fix the prosthesis 200 to the biological tissues by using a needle 9 and a suture 10 to suture the enlarged part 7 of each tongue 5 to the abdominal wall 101, 104 within the central working area 12. During this step, the whole of the prosthesis 200 remains perfectly spread out and perfectly pressed onto the abdominal wall 104, notably by virtue of the presence of the undulations 4 of the frame 2, which smooth out deformations caused by the surgeon in the area of the prosthesis 200 that is in the process of being sutured. The surgeon may execute one or more stitches 11 (see Figure 11) for each enlarged part 7 of the four tongues 5.

As may be seen in Figure 11, the structure of the prosthesis 200 of the invention enables the surgeon to place the stitches 11 in an area situated between the centre of the mesh 1 and the exterior peripheral edge 1a thereof; this area is in particular located at the level of the interior contour of the frame 2 : thus the surgeon does not have to execute stitches at the exterior peripheral edge of the mesh 1, which can be viewed only with difficulty because of the small size of the incision 110. The mesh 1 nevertheless remains perfectly pressed against the abdominal wall 104 along this peripheral edge 1a because of the presence of the frame 2. Nevertheless, because of the structure of the prosthesis 200 of the invention, the stitches 11 are advantageously situated at some distance from the defect, in particular in an area more or less in the middle between the centre 1b of the mesh (which is the location of the hernia defect) and the peripheral exterior edge 1a of the mesh, at a location where the biological tissues are often healthier and less fragile than at the margin of the defect. The stitches 11 may for example be U-shaped, i.e. obtained with a thread provided with a needle at each of its ends.

Once the surgeon has executed the necessary stitches 11 over all the widened parts 7, each tongue 5 is cut approximately at the junction 6a between its widened part 7 and its rectangular part 6 in order to retain at the

implantation site only the widened portion 7, as shown in Figure 11. This figure shows the stitches 11 that fix the widened parts 7 of the tongues 5 to the abdominal wall 104. As may be seen in Figure 11, the prosthesis 200 is thus perfectly deployed, spread out and pressed against the abdominal wall (101, 5 104) with no risk of trapping viscera between the prosthesis 200 and the abdominal wall (101, 104).

The surgeon then has only to close the incision 110 in the conventional way for small size hernias, i.e. by stitches. During this operation, the rectangular parts 6 of the tongues 5 cannot impede the surgeon because 10 they have advantageously been cut off and removed beforehand.

Figure 12 shows a variant of an embodiment of the tongues of the prosthesis of the invention. As shown in Figure 12, two opposed tongues 5 may be produced from a single rectangular piece of textile 14 provided at its two ends with two widened parts 7. The part 14 is fixed to the mesh 1 by the 15 widened parts 7 as explained above for the embodiment of Figures 1 to 11. If a final prosthesis provided with four tongues is required, a second piece 14 of textile is fixed to the mesh 1, perpendicularly to the first piece. A centring thread may be passed through the centres of the two textile parts 14. Once the prosthesis has been positioned correctly at the implantation site, as shown in 20 Figure 13, in which only one textile part 14 is shown, the surgeon has only to cut each textile part 14 at its centre in order to obtain two opposed tongues: the surgeon can then continue fixing the prosthesis as shown in Figures 10B and 11.

The prosthesis of the invention is particularly simple to install, the 25 surgeon being easily able to uncover a comfortable working area, despite the restricted size of the implantation site. The fitting of the prosthesis of the invention is also particularly reliable, all risk of trapping the viscera being avoided. A prosthesis of the invention is particularly suitable for treating umbilical hernias where the abdominal incision made is of small size. The 30 prosthesis of the invention is adapted to adopt a configuration in which it occupies a particularly small volume facilitating its introduction into the abdominal cavity via a small incision without necessitating the use of any dedicated ancillary device. Thanks to its particular structure, the prosthesis of the invention may be spread out and pressed onto the abdominal wall 35 efficaciously, also without necessitating the use of a dedicated tool to assist spreading it and with no risk of reversion of the prosthesis. The prosthesis of

the invention thus makes it possible to treat a hernia, in particular an umbilical hernia, efficaciously, simply and rapidly, minimizing the risk of relapse.



## CLAIMS

1. A prosthesis comprising:

- at least one flexible mesh delimited by a peripheral exterior edge
- at least two tongues extending from one face of the mesh, and

5 - at least one reinforcing member which takes the form of a frame fastened to said mesh and substantially adopting the shape of said peripheral exterior edge of the mesh, said frame being set back from said peripheral exterior edge and being provided with two hinge points, a folding line passing through said two hinge points also passing through the centre of the mesh for folding the mesh in two.

0 2. The prosthesis according to Claim 1, wherein the frame set back from the peripheral external edge is of serpentine shape forming undulations.

3. The prosthesis according to Claim 2, wherein said frame takes the form of a flat ribbon forming undulations substantially in the plane of said mesh.

5 4. The prosthesis according to any one of the preceding claims, wherein said reinforcing member is produced in bioresorbable material.

5. The prosthesis according to any one of the preceding claims, wherein said tongues have a globally rectangular shape part and a widened part provided at one end of the globally rectangular part, said widened part of said tongues fixed to said mesh.

20 6. The prosthesis according to any one of the preceding claims, wherein said tongues are in textile.

7. The prosthesis according to Claims 5 or 6, wherein the widened part being separate from the rest of the tongue, said widened part is produced in gripping textile so that said widened part may be fastened to and/or unfastened from the rest of the tongue at will.

25 8. The prosthesis according to any one of the preceding claims, wherein said two tongues are fixed symmetrically to either side of said folding line.

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9. The prosthesis according to any one of the preceding claims, wherein said mesh is disc-shaped, said frame being substantially in the form of a circular ring, said tongues are fixed at two diametrically opposite places of said ring, said two places being spaced by 90° from each of said two hinge points.
- 5 10. The prosthesis according to the preceding claim, wherein the face of the mesh including said two tongues has two additional tongues fixed to the mesh at the location of two hinge points of the ring.
11. The prosthesis according to any one of the preceding claims, wherein the face of the mesh opposite that including said tongues is covered by a non-adherent coating.
- 0 12. The prosthesis according to any one of the preceding claims, wherein a free end of each tongue is joined together by means of a centring thread.
13. The prosthesis according to any one of the preceding claims, wherein at least a portion of the tongues is of a colour different from that of the mesh.
14. The prosthesis according to claim 5, wherein the widened parts of the tongues are of a  
5 colour different from that of the mesh.
15. The prosthesis according to claim 1, wherein said mesh being disc-shaped and said frame being substantially in the form of a circular ring, said prosthesis comprises four of said tongues, a widened part of which each tongue being of a colour different from that of the mesh, and being distributed along an interior contour of said ring, symmetrically with respect to said folding line  
20 two of said widened parts on one side of said folding line, the other two of said widened parts on the other side of said folding line.
16. The prosthesis according to claim 1, wherein said widened part of each tongue is under the form of isosceles triangles of textile, each triangle being fixed to said mesh via its base, all four triangles showing identical elongation and tensile strength properties in the centripetal  
25 direction.
17. The prosthesis according to claim 1, wherein the hinge points lack elasticity.

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18. The prosthesis according to claim 1, the frame comprises two semicircles connected to each other by the hinge points.

19. The prosthesis according to claim 18, wherein the two semicircles include undulations.

20. The prosthesis according to claim 18, wherein the hinge points bridge the two semicircles.

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**Patent Attorneys for the Applicant/Nominated Person**

**SPRUSON & FERGUSON**

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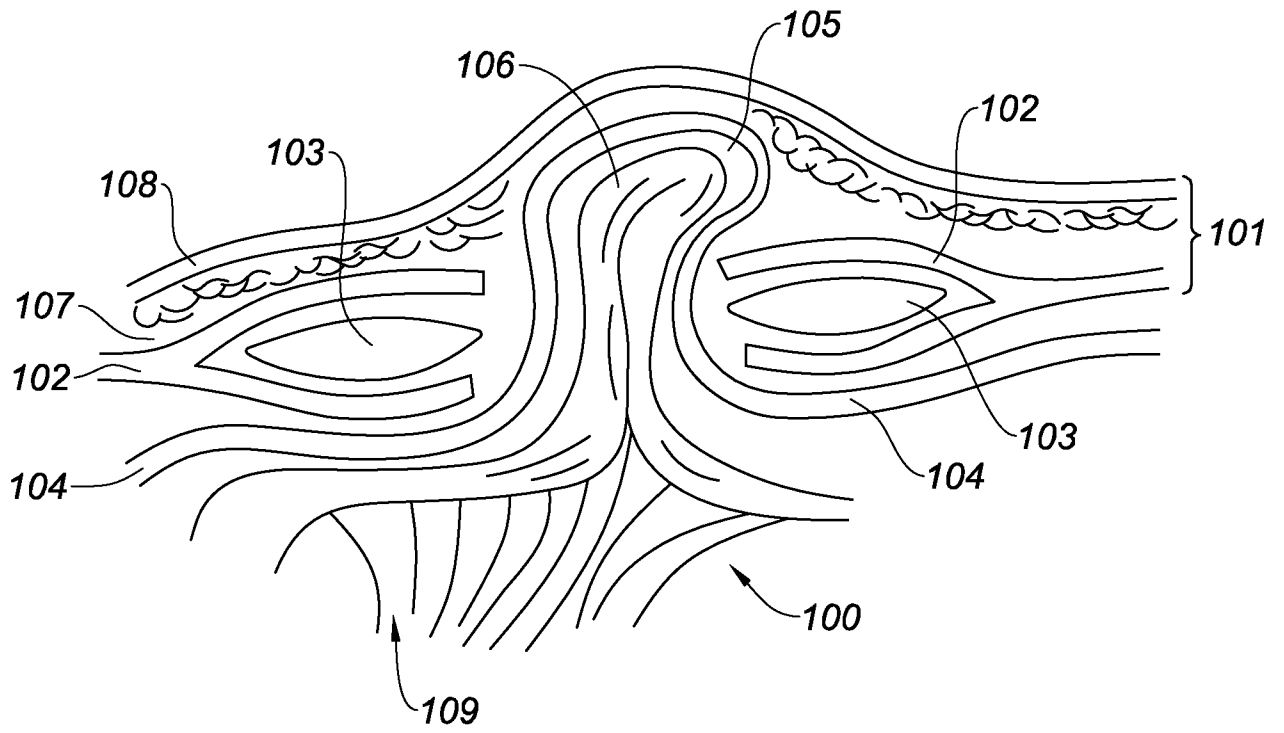


Fig. 1

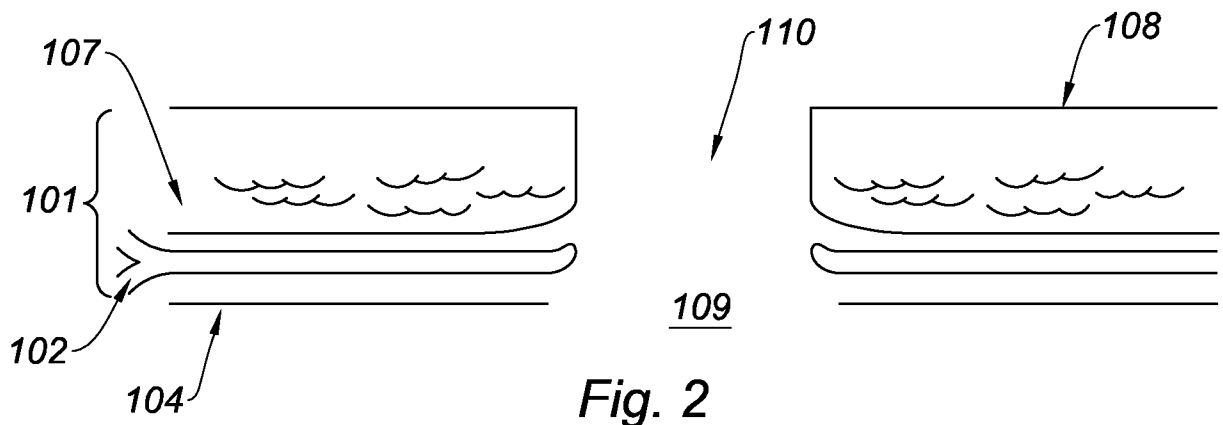


Fig. 2

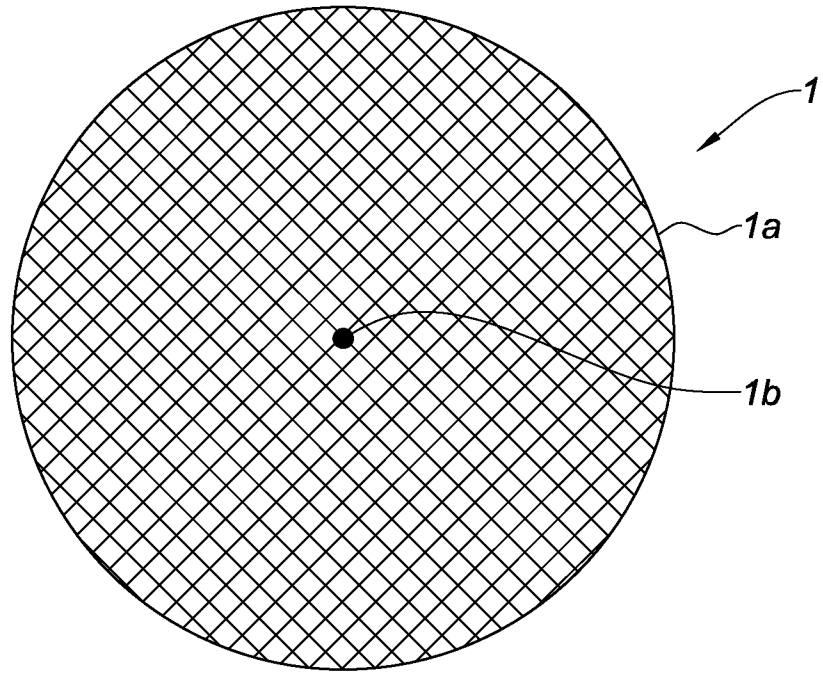


Fig. 3

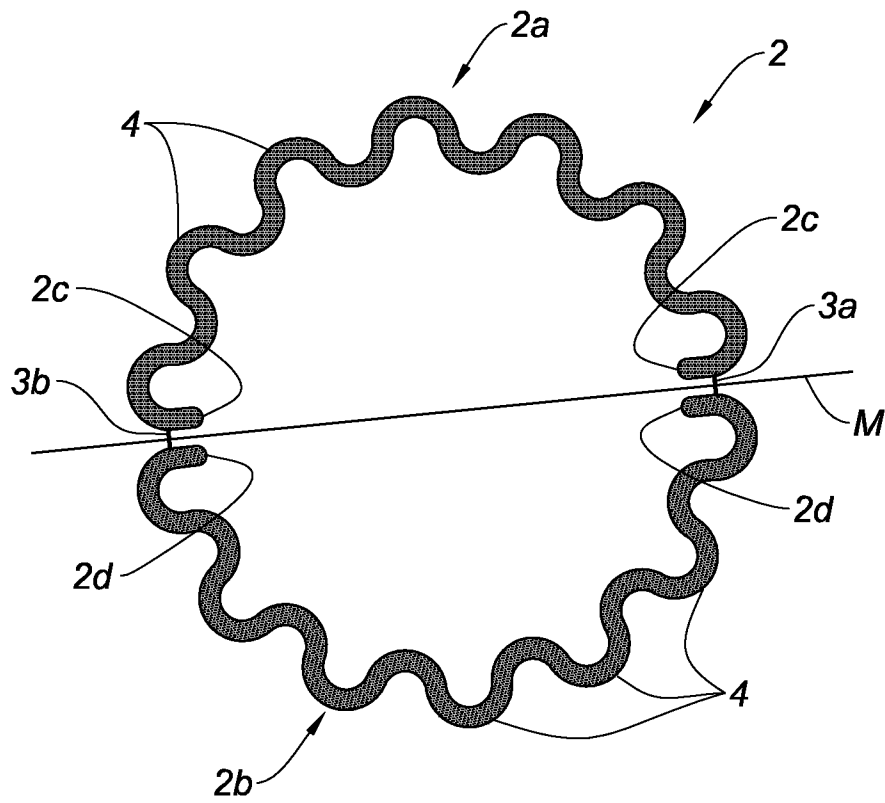


Fig. 4

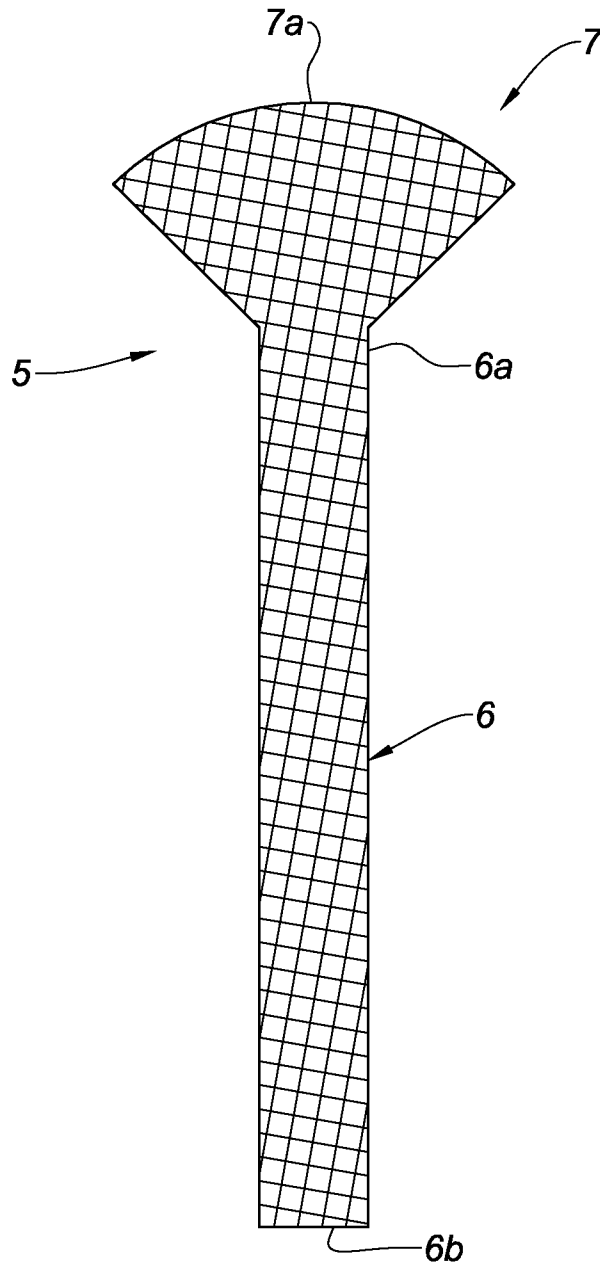


Fig. 5

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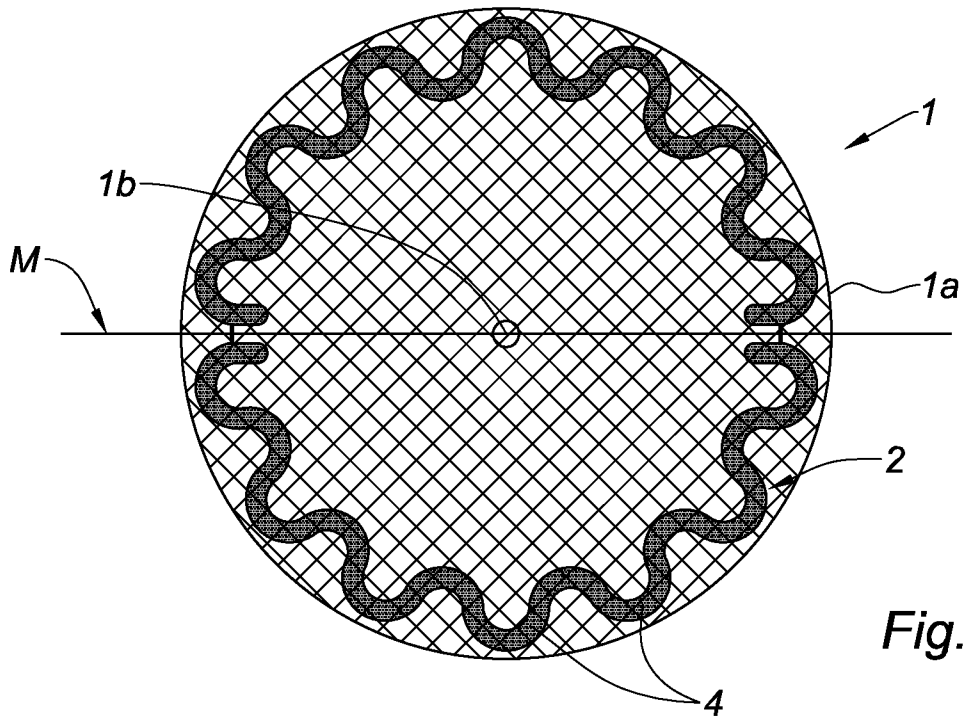


Fig. 6

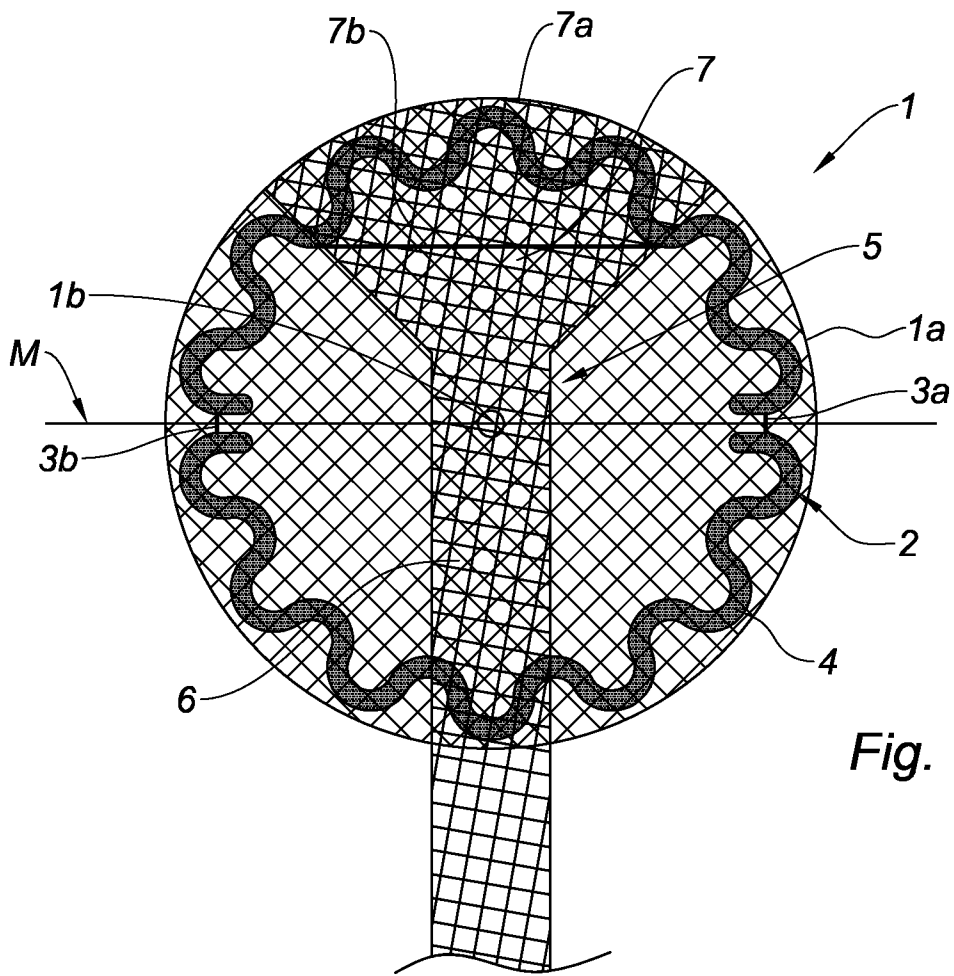


Fig. 7A

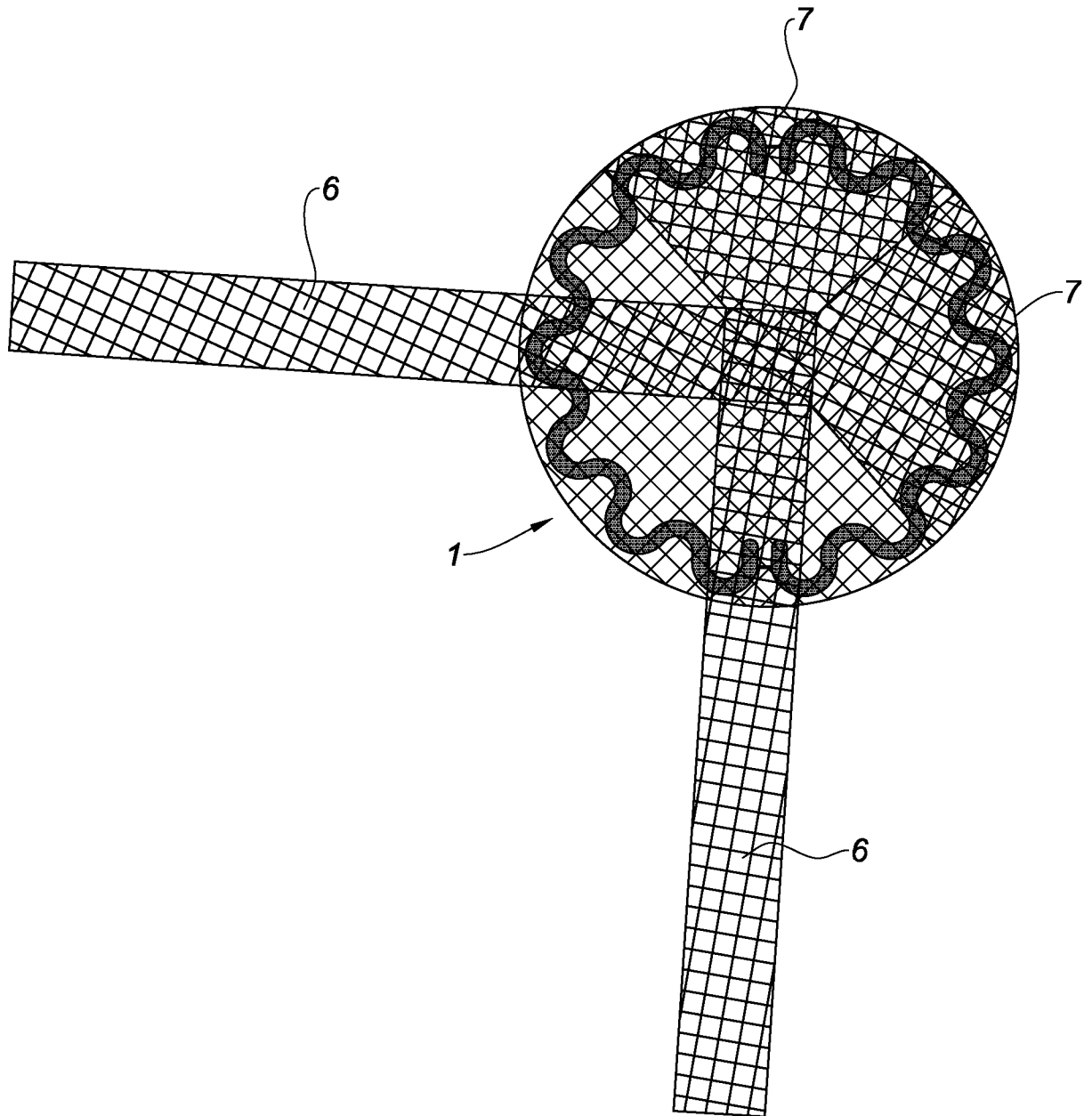


Fig. 7B



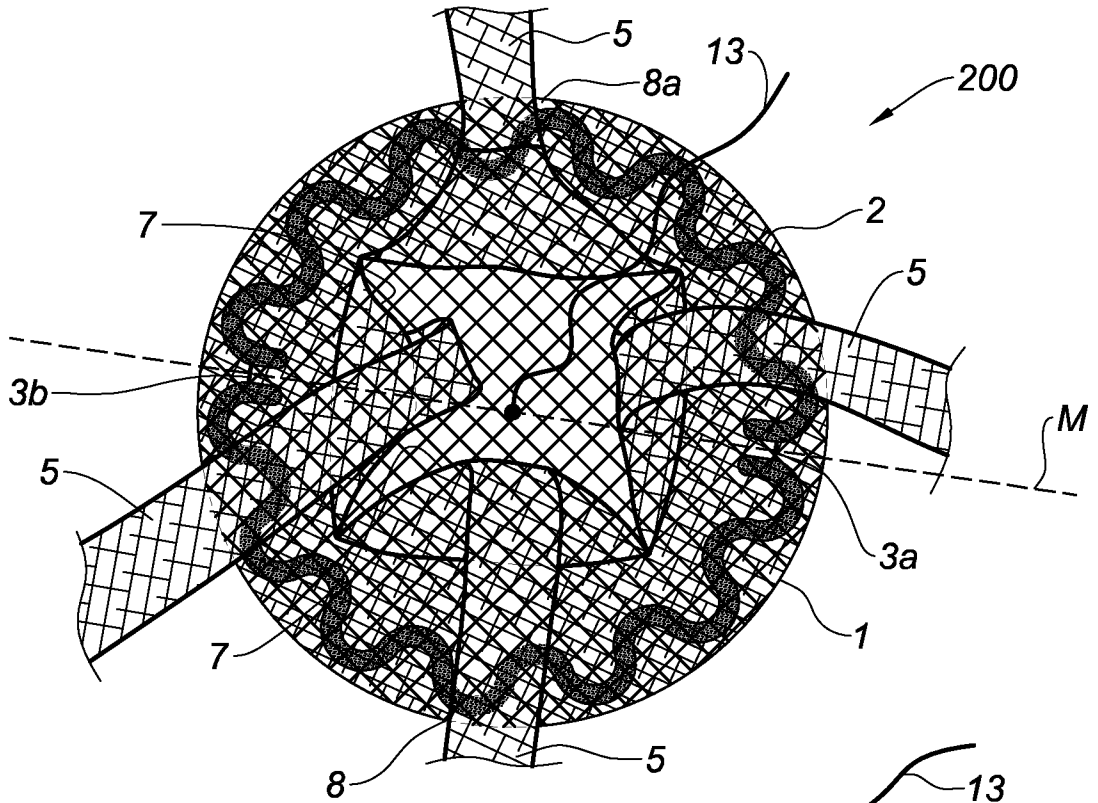


Fig. 8A

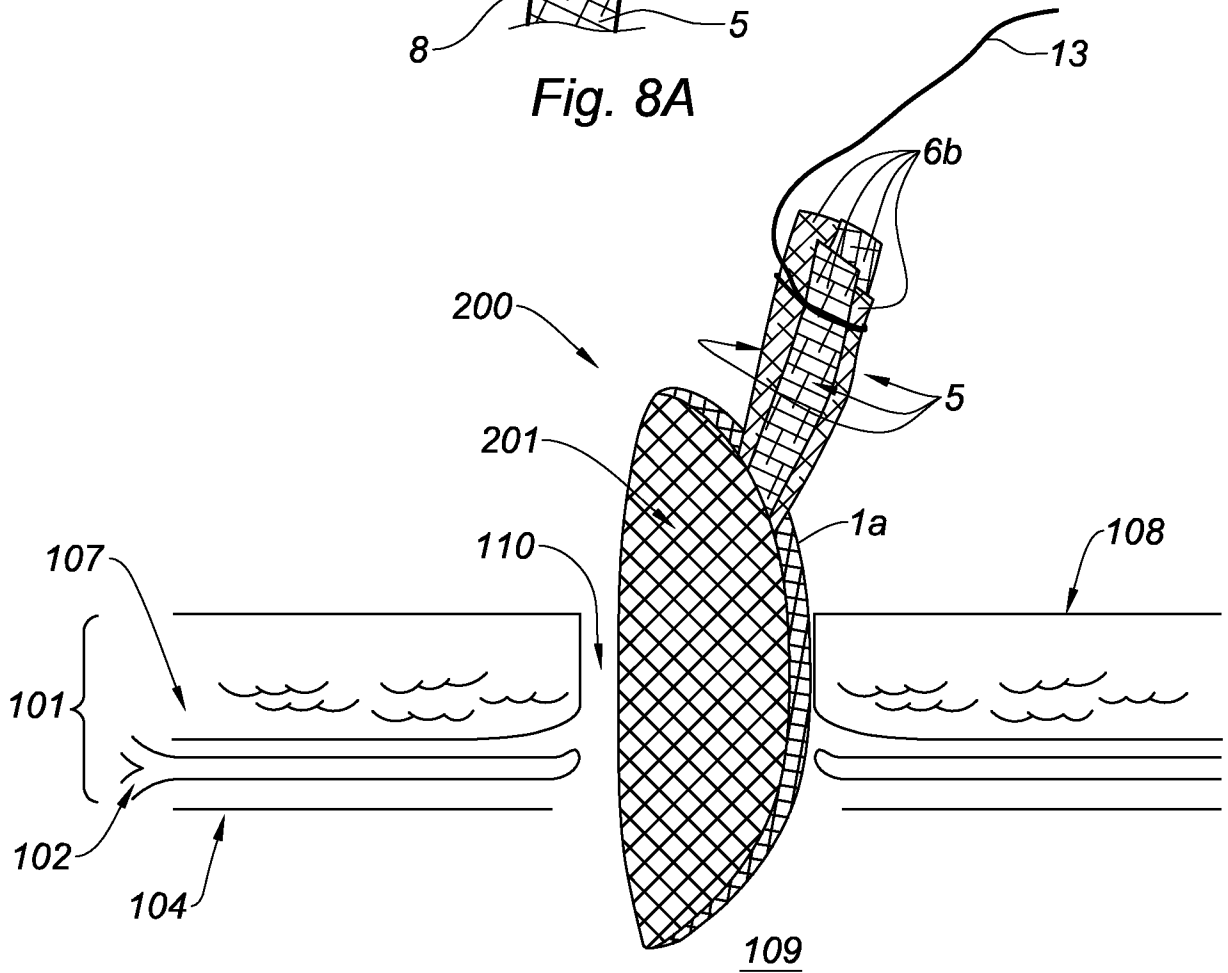


Fig. 9

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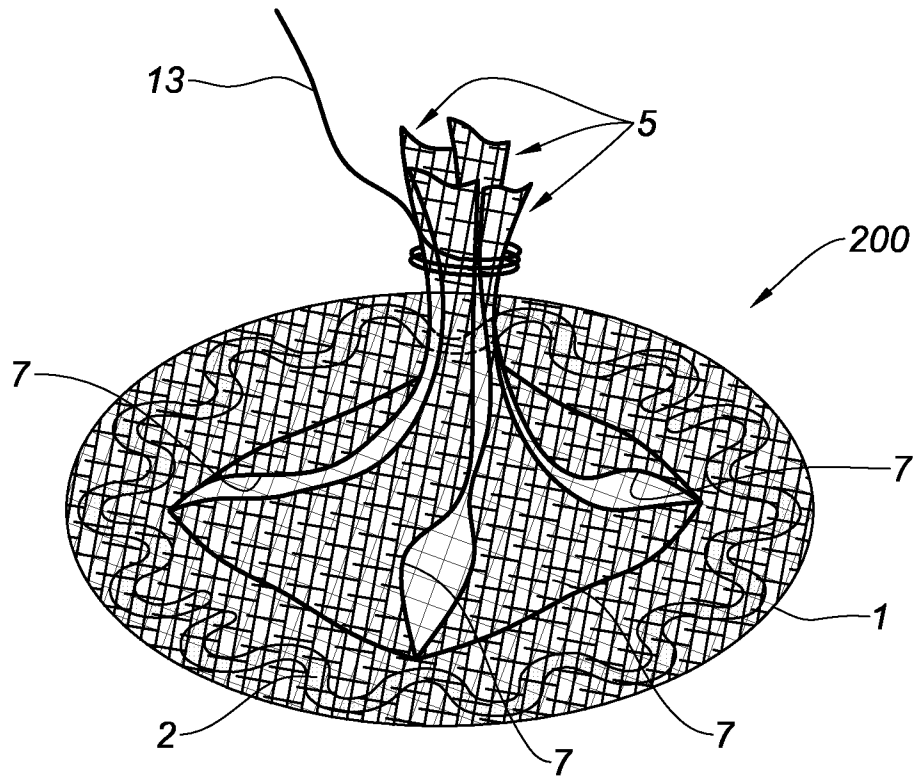


Fig. 8B

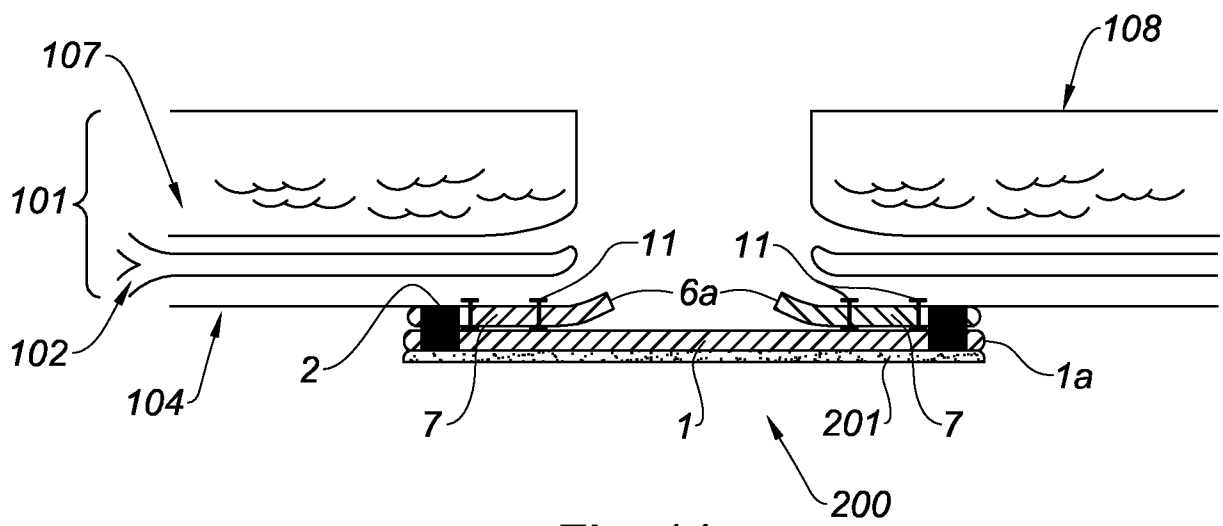


Fig. 11

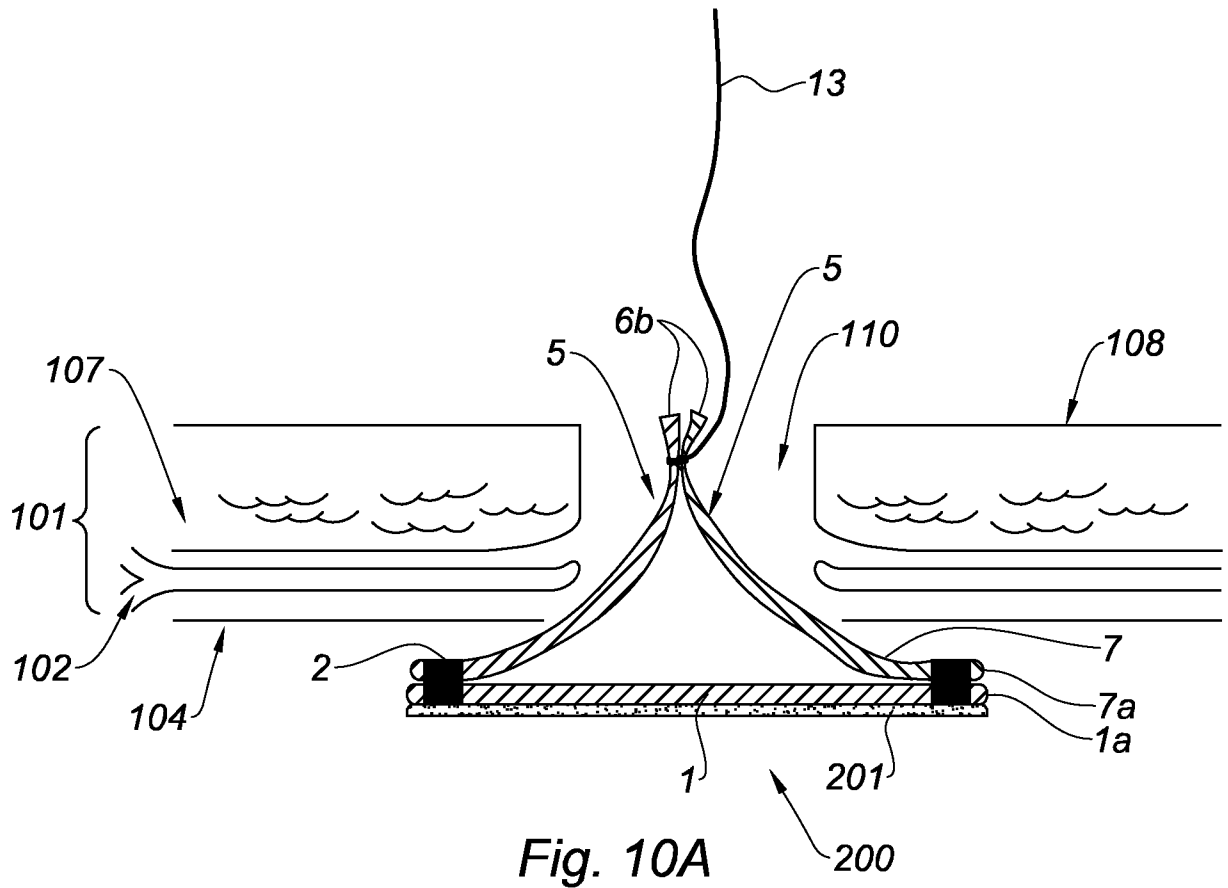


Fig. 10A

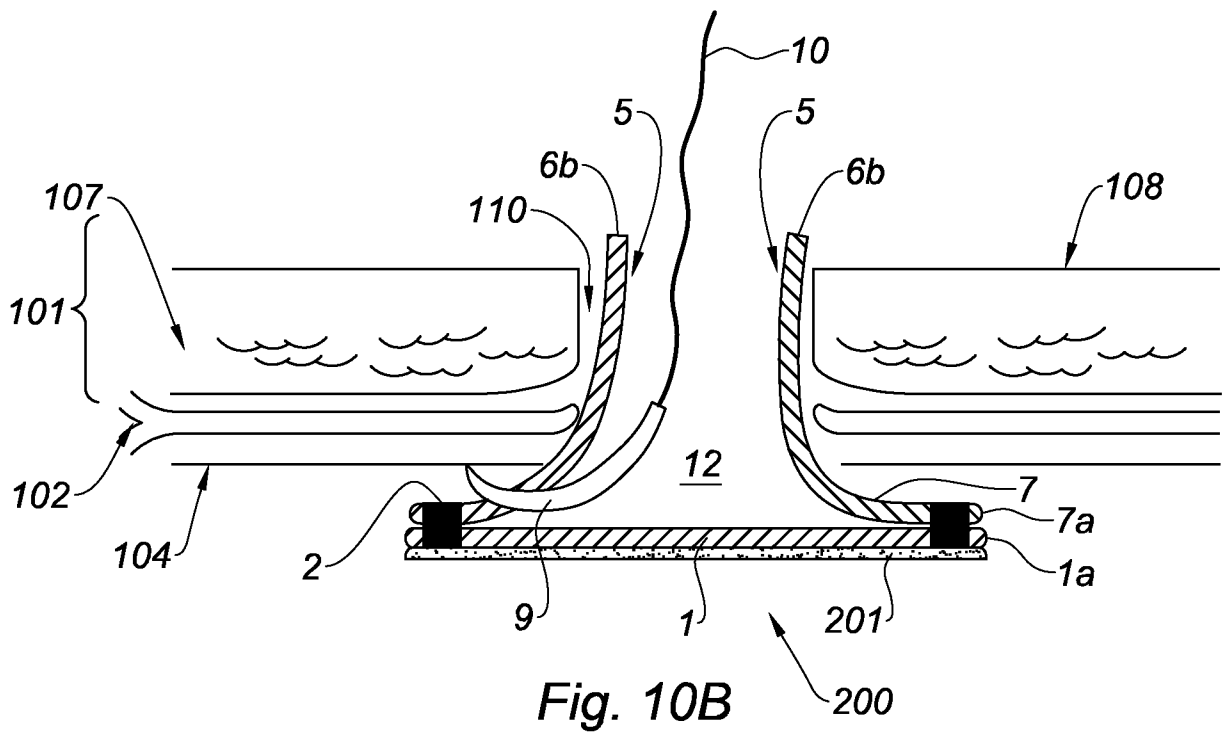


Fig. 10B

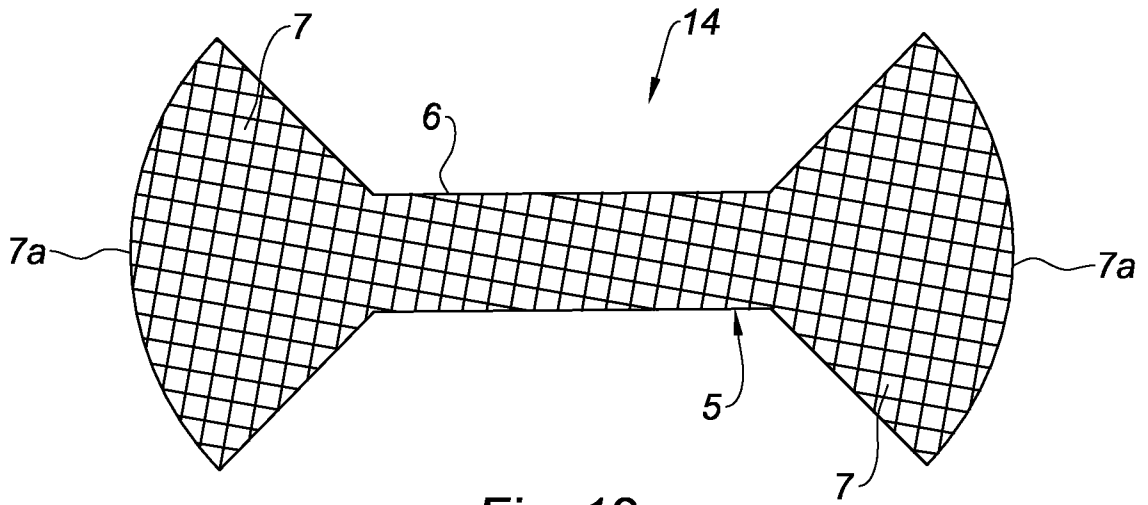


Fig. 12

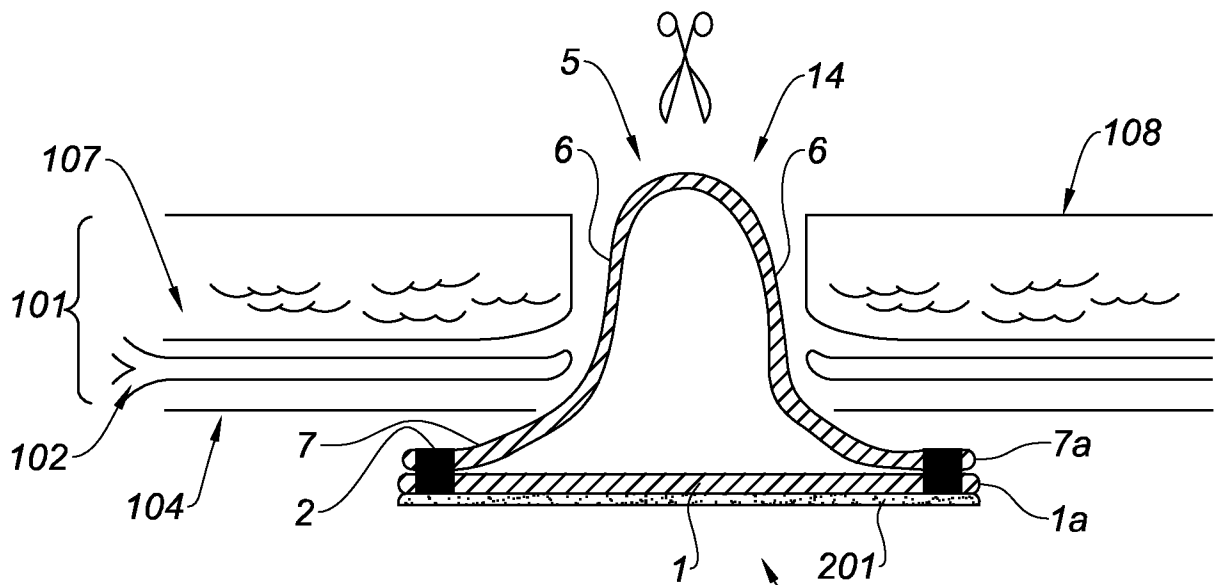


Fig. 13

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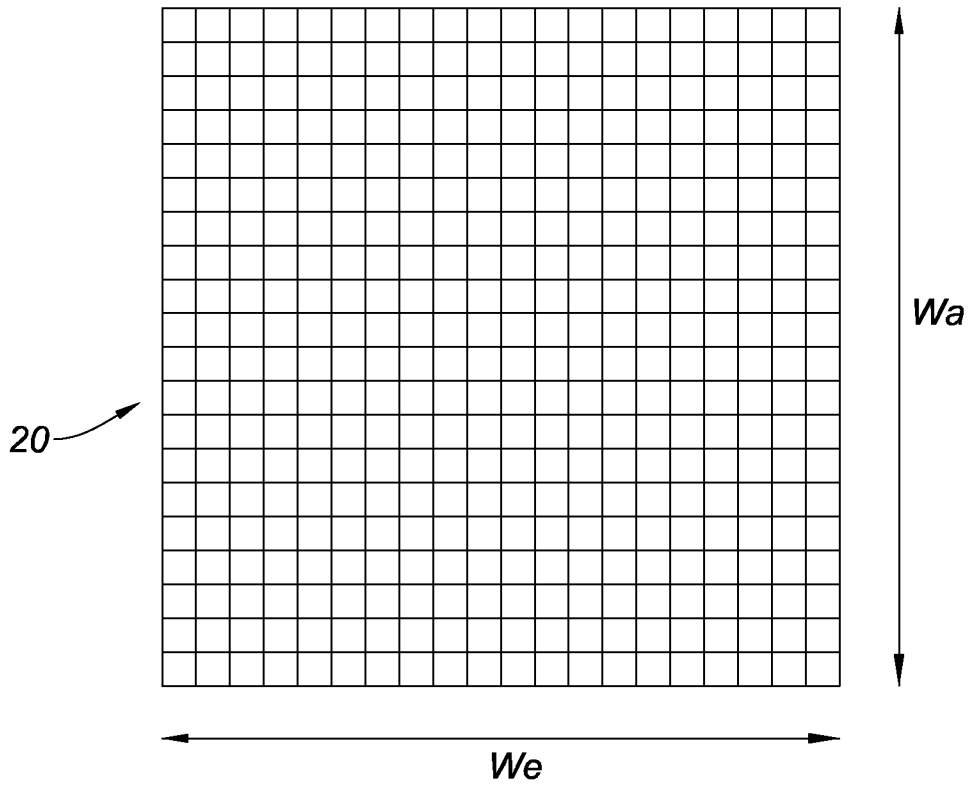


Fig. 14

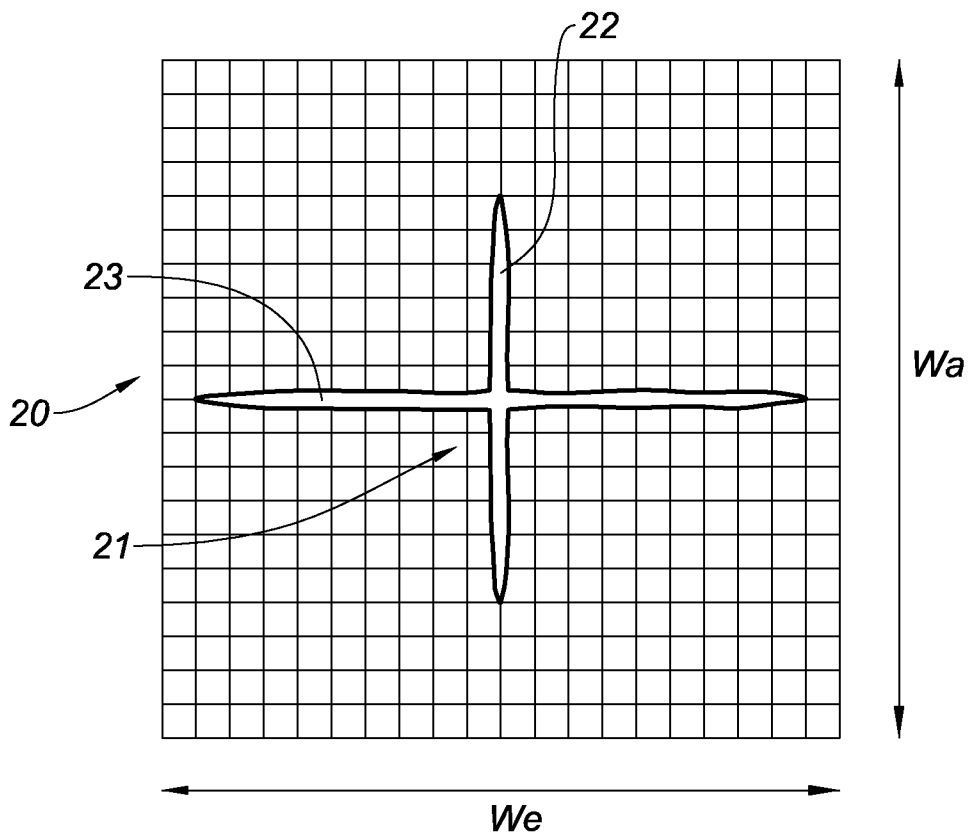


Fig. 15

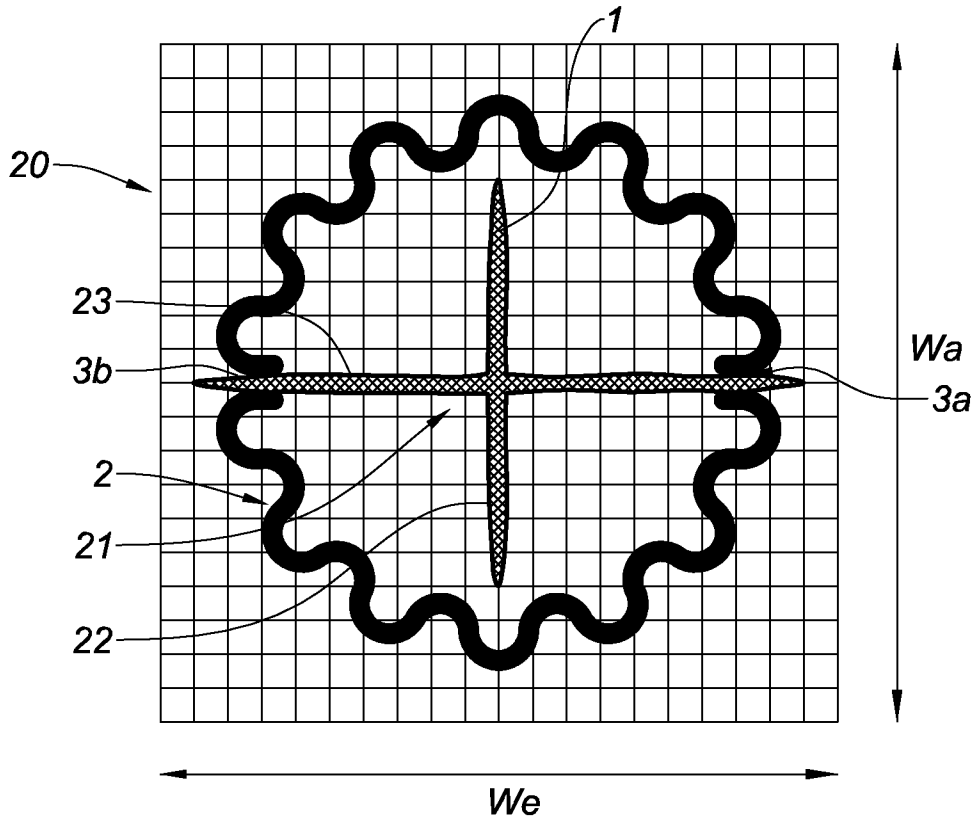


Fig. 16

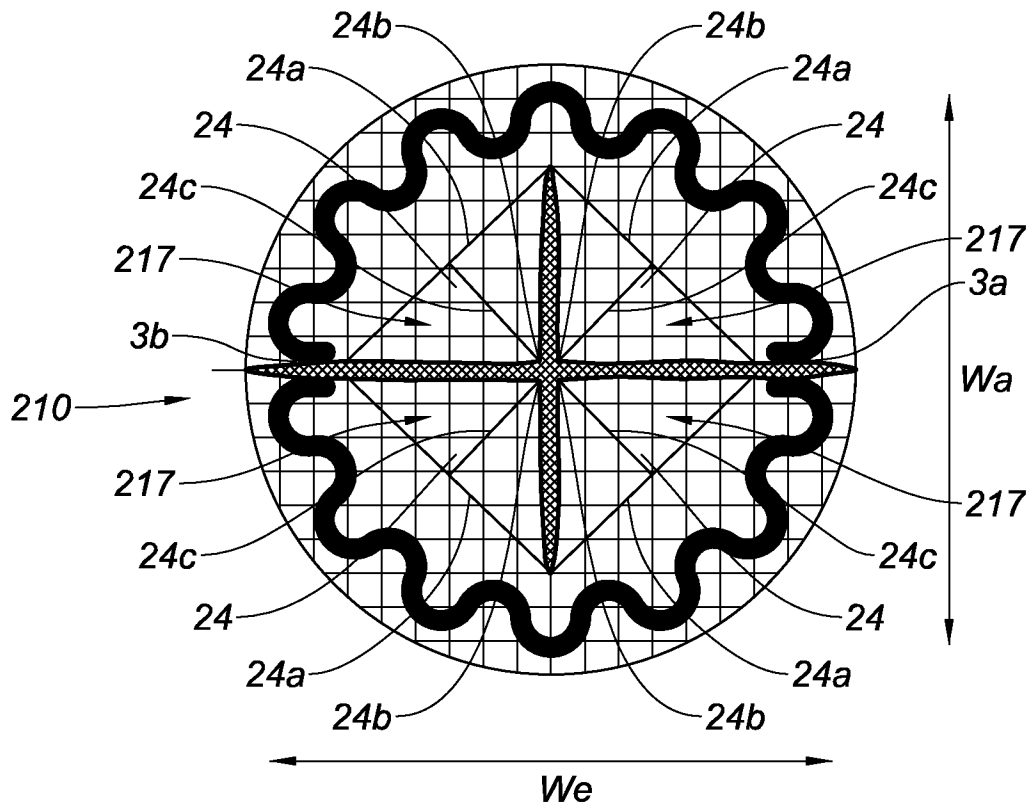


Fig. 17