



(12) **DEMANDE DE BREVET CANADIEN**
CANADIAN PATENT APPLICATION

(13) **A1**

(22) Date de dépôt/Filing Date: 2018/04/30

(41) Mise à la disp. pub./Open to Public Insp.: 2018/11/02

(30) Priorité/Priority: 2017/05/02 (EP17305489.1)

(51) Cl.Int./Int.Cl. *A61F 2/02* (2006.01),
A61L 27/50 (2006.01)

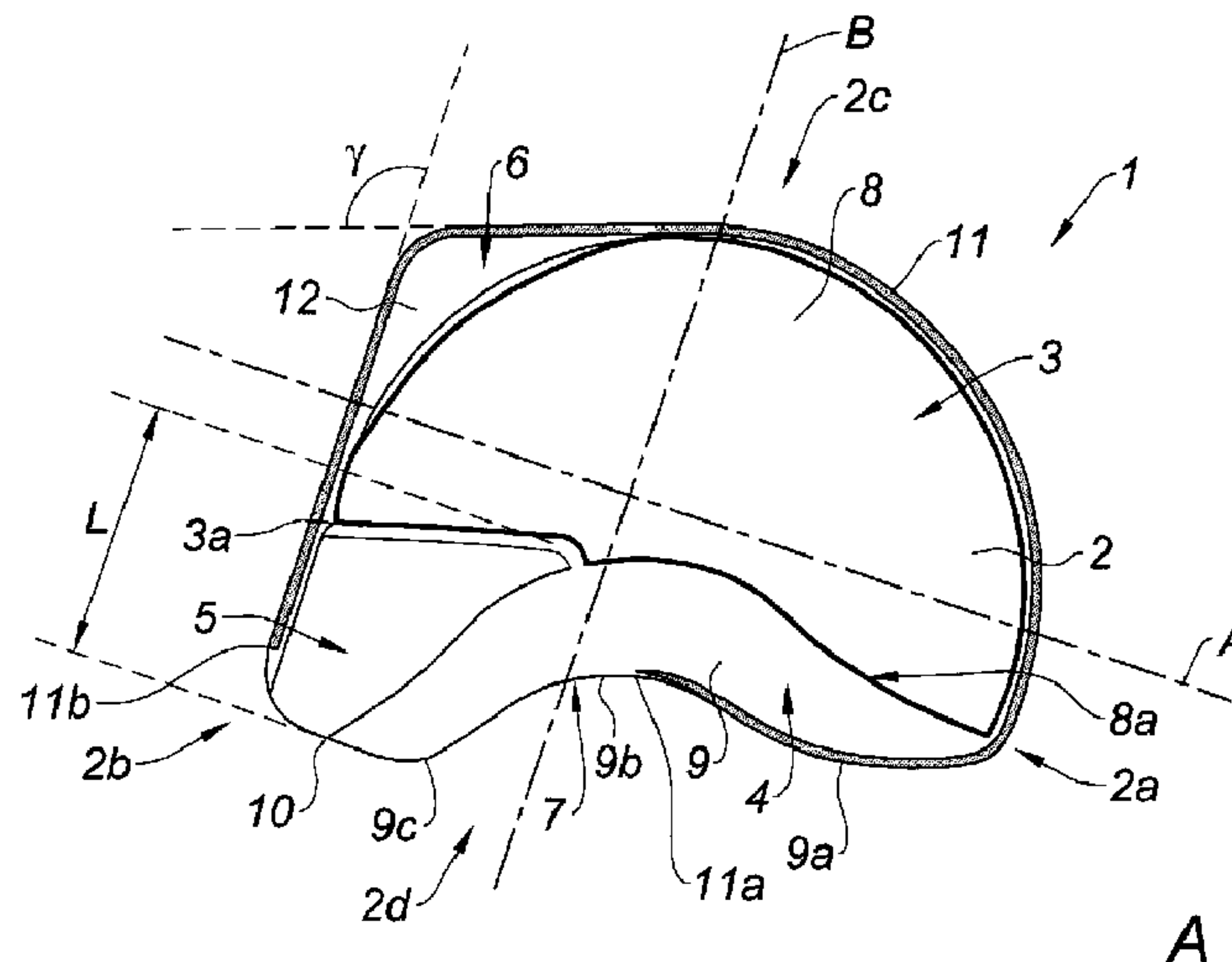
(71) Demandeur/Applicant:
SOFRADIM PRODUCTION, FR

(72) Inventeurs/Inventors:
BAILLY, PIERRE, FR;
DESORME, MYLENE, FR;
MONTANARI, SUZELEI, FR...

(74) Agent: OSLER, HOSKIN & HARCOURT LLP

(54) Titre : PROTHESE DESTINEE A LA REPARATION D'UNE HERNIE INGUINALE

(54) Title: PROSTHESIS FOR INGUINAL HERNIA REPAIR



(57) **Abrégé/Abstract:**

The present invention relates to a prosthesis (1) for repairing a inguinal hernia defect comprising : a piece (2) of biocompatible material having a preformed three- dimensional shape, including : - a first portion (3) forming a partial spherical cap surface (8)

(57) **Abrégé(suite)/Abstract(continued):**

shaped and dimensioned so as to substantially conform to the shape of the anterior abdominal wall, - a second portion (4) extending from an inferior edge of said first portion and forming a wavy-shaped wall (9), shaped and dimensioned so as to substantially conform to the shape of the psoas muscle, characterized in that said piece (2) further comprises : a third portion (5) forming an arched part (10) extending longitudinally in the inferior direction from a medial inferior corner (3a) of said first portion, said arched part extending radially substantially in the front direction, said third portion being intended to face the medial inferior area of the inguinal anatomy.

ABSTRACT

Prosthesis for inguinal hernia repair

The present invention relates to a prosthesis (1) for repairing a inguinal hernia defect comprising :

a piece (2) of biocompatible material having a preformed three-dimensional shape, including :

- a first portion (3) forming a partial spherical cap surface (8) shaped and dimensioned so as to substantially conform to the shape of the anterior abdominal wall,
- a second portion (4) extending from an inferior edge of said first portion and forming a wavy-shaped wall (9), shaped and dimensioned so as to substantially conform to the shape of the psoas muscle,

characterized in that said piece (2) further comprises :

a third portion (5) forming an arched part (10) extending longitudinally in the inferior direction from a medial inferior corner (3a) of said first portion, said arched part extending radially substantially in the front direction, said third portion being intended to face the medial inferior area of the inguinal anatomy.

Figure 2A

Prosthesis for inguinal hernia repair

The present invention relates to a preformed three-dimensional prosthesis to be used for repair of inguinal hernias.

In this application, the “medial” end or part of an element of a prosthesis is to be understood as meaning the end or part of the element located in the direction of the median plane of the body when the prosthesis is implanted in the body. The “lateral” end or part of an element of a prosthesis is to be understood as meaning the end or part of the element located in the direction of the outwards lateral plane of the body when the prosthesis is implanted in the body. Likewise, in this application, the “medial direction” is to be understood as meaning the direction towards said median plane and the “lateral direction” is opposite the “medial direction”, the medial and lateral directions being aligned on the same axis, the medial-lateral axis. In this application, the “superior” end or part of an element of a prosthesis is to be understood as meaning the end or part of the element located substantially in the direction of the head of the body when the prosthesis is implanted in the body. The “inferior” end or part of an element of a prosthesis is to be understood as meaning the end or part of the element located in the direction of the feet of the body when the prosthesis is implanted in the body. Likewise, in this application, the “superior direction” is to be understood as meaning the direction towards said head and the “inferior direction” is opposite the “superior direction”, the superior and inferior directions being aligned on the same axis, the superior-inferior axis. In this application, the “front” end or part of an element of a prosthesis is to be understood as meaning the end or part of the element located substantially in the direction of the front of the body when the prosthesis is implanted in the body. The “rear” end or part of an element of a prosthesis is to be understood as meaning the end or part of the element located in the direction of the back of the body when the prosthesis is implanted in the body. Likewise, in this application, the “front direction” is to be understood as meaning the direction towards said front and the “rear direction” is opposite the “front direction”, the front and rear directions being aligned on the same axis, the front-rear axis.

The abdominal wall in humans is composed of fat and muscles interconnected by fascias. It sometimes happens that a break in continuity occurs in the fascias, allowing part of the peritoneum to slip through and form a sac, or a hernia, containing either fat or part of the intestines. Hernias or incisional hernias (a hernia occurring through a parietal surgical scar) show themselves in the form of a bulge at the surface of the skin and are classed, for example, as umbilical or inguinal hernias, depending on where they are located.

Wall reinforcement prostheses, for example for the abdominal wall, are widely used in surgery. These prostheses are intended to treat hernias by temporarily or permanently filling a tissue defect. These prostheses are generally made from a biocompatible prosthetic textile and can have a number of shapes, for example
 5 rectangular, circular or oval, depending on the anatomical structure to which they are to adapt. Some of these prostheses may show three-dimensional shapes.

Indeed, when an inguinal hernia is to be treated, it is of particular importance to take into account the anatomy of the inguinal region, in particular the presence of the iliac vessels. In addition, when the patient is a man, the spermatic cord
 10 needs to be taken into account while positioning the prosthesis. The various anatomical organs to be taken into account confer to the inguinal region to be treated a three-dimensional shape. In addition, the shape of the inguinal region being asymmetric, the shape of a prosthesis intended to be used for treating an inguinal hernia will be dependent on the side (right or left) of the body that is to be treated. In this view, the
 15 shape of a prosthesis for treating an inguinal hernia may be defined in relation with the position of the prosthesis once implanted in the body of a patient. For example, in an implanted configuration, a three-dimensional prosthesis for treating an inguinal hernia may comprise a medial part, a lateral part, a superior part, an inferior part, a front part and a rear part as defined above.

20 With reference to Figure 1, on which are indicated the medial-lateral axis A and the superior-inferior axis B, the anterior retro-parietal space of the inguinal region for the right hand side of a body is shown ; in other words the inguinal region is shown from a view point located in the rear side of the body, for example from the interior of the abdominal cavity but with the peritoneum not shown on the Figure for sake of
 25 clarity, and looking towards the front side of the body, in other words in the direction of the abdominal skin of the body. On Figure 1, one can see :

- in direction of the front side of the body, the rectus abdominis muscles 116 and the transverse muscle 118 forming part of the anterior abdominal wall of the abdomen,
- 30 - in the direction of the lateral side of the body, the psoas muscle 112, the iliac vessels 111, and the elements of the spermatic cord 120,
- in the direction of the medial inferior side of the body, the upper part of the pubic bone 117.

On Figure 1, are represented in dotted lines the three locations for
 35 potential hernias to occur in the inguinal region : the indirect inguinal hernia, shown as dotted line circle 122 on Figure 1, occurs mainly in the lateral area of the inguinal

region : it is a swelling of the groin caused when a portion of the peritoneum (not shown but located between the Figure 1 and the person looking at Figure 1), possibly containing abdominal viscera, passes through the orifice of the inguinal canal. It is necessary to push the peritoneum, and possibly the abdominal viscera, back in the direction of the abdominal cavity, and place a barrier, namely a prosthesis, between the peritoneum and the orifice of the inguinal canal. The direct hernia, shown as dotted line circle 119 on Figure 1, occurs mainly in the medial area of the inguinal region. The femoral hernia, shown as dotted line circle 121 on Figure 1, occurs mainly in the medial inferior area of the inguinal region.

It will be noted in Figure 1 that the elements described above are not all in the same spatial plane, but instead are arranged in an oblique arrangement from a superior-lateral corner to an inferior-medial corner. In the case of an inguinal hernia, the prosthesis implanted after reduction of the hernia must ensure satisfactory covering of the hernia to be treated, either direct, indirect or femoral, by adapting to the contours of the region and by respecting the obliqueness of the inguinal region, if possible without leaving any empty spaces.

When operating by laparoscopy for repairing an inguinal hernia, two routes may be used for bringing the prosthesis to the implantation site, namely the inguinal region. For example, according to a first surgical method, namely the transabdominal preperitoneal route (TAPP), the prosthesis is first conveyed to the abdominal cavity via a trocar ; the peritoneum is then open and the prosthesis is brought to the inguinal region through the incision performed through the peritoneum. The peritoneum is closed once the implantation is completed. According to a second surgical method, namely the totally extra-peritoneal route (TEP), the prosthesis is brought to the inguinal region through a trocar directly through the muscles of the abdominal wall, and the peritoneum is not open.

Because of the obliqueness of the inguinal region and the restricted deployment space, it can prove complicated to deploy the prosthesis and then orient it suitably with respect to the orifice of the inguinal canal or to the other organs to be protected, such as the iliac vessels or the spermatic cord.

The effectiveness of the prosthesis, hence the ability to minimize the risks of recurrence, depends to a large extent on how well the prosthesis is correctly spread out against the biological tissues of the inguinal region. In the present application, "biological tissues of the inguinal region" are understood as the biological tissues of the organs or elements of the inguinal region that are shown in Figure 1 and that are intended to be protected from the peritoneum with a view to repairing the hernia, and

in particular the anterior muscle wall, the upper part of the pubic bone, the iliac and spermatic vessels, and part of the psoas muscle.

Indeed, prostheses based on a textile are generally flexible. In order to introduce them into a trocar, they are often folded up or rolled to reduce their volume.

5 They therefore tend to form creases when introduced at the implantation site. The spreading out of textile based prosthesis from the trocar is of key importance but can prove difficult.

Document US 6, 723, 133 describes a preformed three-dimensional prosthesis for the repair of inguinal hernia intended to conform to the anatomical shape
10 of the defective wall. The prosthesis described in this patent comprises a plurality of distinctly shaped portions joined to each other, all said shaped portions being configured with a substantially spherical shape.

As seen above, the anatomy of the inguinal region implies various organs such as muscles having various shapes, vessels, such as the iliac vessels, having various
15 paths, and the pubic bone. In addition, the anatomy of the inguinal region may vary significantly from one human being to the other, in particular in its medial inferior area, in the surroundings of the upper part of the pubic bone. It has been observed that, with some preformed three-dimensional prostheses of the prior art, this medial inferior area of the inguinal region is not covered efficiently. In particular, depending on the true
20 anatomy of the patient being treated, the surgeon may need to apply a certain tension on the prosthesis or shift the prosthesis at the moment of positioning the prosthesis, so that a part of the prosthesis be present in the medial inferior area of the inguinal region, namely in the surroundings of the pubic bone. Alternatively the surgeon may need to create folds in the prosthesis so as to conform it to the specific shape of the
25 medial inferior area of the inguinal region he is confronted to in relation with the patient he is treating.

There is therefore still the need for a prosthesis for repair of inguinal hernias that is based on a preformed three-dimensional piece of biocompatible material intended to globally conform to the anatomical shape of the defective wall in
30 the inguinal region, that is able to be spread out from the trocar and cover efficiently not only said defective wall but also the medial inferior area of the inguinal region, whatever the true anatomical shape of said medial inferior area in the patient to be treated, such that the surgeon does not have to apply specific tensions on the prosthesis or create folds when positioning the prosthesis with respect to the biological
35 tissues.

The present invention aims to meet such a need.

A first aspect of the invention is an implantable prosthesis for repairing a hernia defect in an inguinal region of a human body delimited by the anterior abdominal wall, the psoas muscle and a medial inferior area of the inguinal anatomy, the prosthesis comprising :

5 a piece of biocompatible material having a preformed three-dimensional shape, the piece including :

- a first portion, intended to face the anterior abdominal wall, said first portion forming a partial spherical cap surface shaped and dimensioned so as to substantially conform to the shape of the anterior abdominal wall,
- 10 - a second portion, intended to face the psoas muscle, said second portion extending from an inferior edge of said first portion and forming an wavy-shaped wall, shaped and dimensioned so as to substantially conform to the shape of the psoas muscle,

15 characterized in that said piece further comprises :

a third portion forming an arched part, said arched part extending longitudinally substantially in the inferior direction from a medial inferior corner of said first portion, said arched part extending radially substantially in the front direction, said third portion being intended to face the medial inferior area of the inguinal anatomy.

20 The prosthesis of the invention has a shape allowing it to conform ideally to the anatomy of the inguinal region to be reinforced. In particular, the shape and dimension of the first, second and third portions allow adapting the prostheses to different types of inguinal hernia, such as the direct inguinal hernia, the indirect inguinal hernia and the femoral inguinal hernia.

25 Moreover, the presence of the third portion of the prosthesis of the invention and the specific shape of this third portion allow covering the medial inferior area of the inguinal anatomy, in particular the region around the upper part of the pubic bone, without having to tear or stretch the other parts of the prosthesis or to create additional folds likely to undesirably interfere with the surrounding organs. Indeed, the presence of this third portion and its shape allow the surgeon to easily lay the entire prosthesis on each anatomical element to be protected without having to apply a particular compensating force on another part of the prosthesis or to shift the prosthesis. The prosthesis is perfectly spread out in the three dimensions of the inguinal region to be repaired, with no need to create folds in the prosthesis in order to conform it to the shape of the anatomy to be protected. There is no tension created in the prosthesis when it is positioned.

30

35

The prosthesis of the invention is intended to be used for repairing a hernia defect in the inguinal region of a human body. The prosthesis of the invention is particularly adapted for use in laparoscopic surgery, either via the transabdominal preperitoneal route (TAPP) or the totally extra-peritoneal route (TEP).

5 The inguinal region may be delimited by the anterior abdominal wall, the psoas muscle and a medial inferior area of the inguinal anatomy, in the surroundings of the pubic bone.

 The prosthesis of the invention comprises a piece of biocompatible material having a preformed three-dimensional shape. The piece of biocompatible
10 material comprises several portions, each having a determined shape, the assembly of these determined shapes forming the preformed three-dimensional shape. The piece of biocompatible material is preferably made as a unitary structure.

 In the present application, "biocompatible" is understood as meaning that the materials having this property can be implanted in the human or animal body.

15 Biocompatible materials for forming hernia repair prosthesis are well known in the art. For example, the biocompatible material may comprise a bioresorbable, a non-bioresorbable material and mixtures thereof.

 In the present application, "bioresorbable" or "biodegradable" is understood to mean that the materials having this property are absorbed and/or
20 degraded by the tissues or washed from the implantation site and disappear *in vivo* after a certain time, which may vary, for example, from a few hours to a few years, depending on the chemical nature of the materials.

 Examples of bioresorbable material suitable for the piece of the prosthesis of the invention can be chosen from among the following bioresorbable materials:
25 polylactic acid (PLA), polycaprolactones (PCL), polydioxanones (PDO), trimethylene carbonates (TMC), polyvinyl alcohol (PVA), polyhydroxyalkanoates (PHA), oxidized cellulose, polyglycolic acid (PGA), polyethylene glycol (PE), copolymers of these materials, and mixtures thereof.

 Examples of non-bioresorbable material suitable for the piece of the
30 prosthesis of the invention can be chosen from among the following non-bioresorbable materials: polypropylenes, polyesters such as polyethylene terephthalates, polyamides, silicones, polyether ether ketone (PEEK), polyarylether ether ketone (PAEK) and mixtures thereof.

 The piece may be made from a preformed sheet of foam, preferably a
35 porous material. Within the meaning of the present application, "porous material" is understood as a material having pores, voids or holes, that are open and are distributed

uniformly or irregularly and promote cell colonization and tissue ingrowth. The pores can be present in all types of configurations, for example as spheres, channels, hexagonal forms.

In embodiments, the piece of biocompatible material comprises a textile, in particular a porous textile. In embodiments, the piece of biocompatible material consists in a textile, for example a porous textile.

According to the present invention, "textile" is understood as any arrangement or assembly of biocompatible yarns, fibres, filaments and/or multifilaments, for example obtained by knitting, weaving, braiding, or non-woven. Biocompatible textiles, in particular porous textiles, suitable for the repair of a hernia defect are well known in the art.

The piece of biocompatible material of the prosthesis of the invention comprises a first portion forming a partial spherical cap surface. The partial spherical cap surface is intended to face the anterior abdominal wall. The partial spherical cap surface may extend in the front direction, namely towards the abdominal wall. The partial spherical cap surface is shaped and dimensioned so as to conform to the shape of the anterior abdominal wall. A spherical cap suitable for forming said first portion may derive from a sphere having a diameter ranging from about 200 mm to about 220 mm, preferably ranging from about 206 mm to about 215 mm, said spherical cap having a height ranging from about 15 mm to about 35 mm, preferably from about 20 mm to about 28 mm. The partial spherical cap suitable for obtaining the surface forming the first portion may result from the removal of an inferior part of the spherical cap along a wavy line forming an inferior edge of the first portion.

The piece of biocompatible material of the prosthesis of the invention comprises a second portion forming a wavy-shaped wall intended to face the psoas muscle. The wavy-shaped wall extends from the inferior edge of the first portion and is shaped and dimensioned so as to conform to the shape of the psoas muscle. In embodiments, the wavy-shaped wall extends substantially from a lateral side to a medial side of the piece of biocompatible material and it includes a surface generated by a generatrix, under the form of a straight line D, following a directrix, under the form of a directing curved line C. In embodiments, the directing curved line C includes at least a lateral curve extending substantially in the inferior direction and at least a central curve, offset in the medial direction with respect to said lateral curve, said central curve extending substantially in the superior direction. In embodiments, the directing curved line C further includes a medial curve extending substantially in the inferior direction.

The presence or not of the medial curve may depend on the anatomy of the patient to be treated, in particular on the size of the hernia defect to be repaired.

For example, the radius of curvature of the lateral curve may range from about 50 mm to about 55 mm, and may preferably be about 53 mm, the radius of curvature of the central curve may range from about 20 mm to about 35 mm, and may preferably be from about 24 mm to about 31 mm, and the radius of curvature of the medial curve, when present, may range from about 70 mm to about 90 mm, and may preferably be about 80 mm.

The wavy-shaped wall is preferably inclined with respect to the direction of the height of the spherical cap of the first portion. In embodiments, the angle formed between the generatrix of the wavy-shaped wall and the direction of the height of the spherical cap of the first portion may range from about 35° to about 50°, preferably from about 40° to about 45°.

The piece of biocompatible material further comprises a third portion forming an arched part. The arched part extends longitudinally substantially in the inferior direction from a medial inferior corner of said first portion, said arched part extending radially substantially in the front direction, said third portion being intended to face the medial inferior area of the inguinal anatomy. By “arched part” is meant in the present application an angular section of a tube. The radius of the arched part according to the present application is the radius of the tube from which the arched part derives.

In embodiments, the arched part has a radius ranging from about 70 mm to about 110 mm, preferably from about 80 mm to about 100 mm. In embodiments, the arched part extends circumferentially along a portion of a circle forming an angle ranging from about 30° to about 45°, preferably ranging from 33° to 40°. The arched part may have a height ranging from about 20 mm to about 40 mm, preferably from about 21 mm to about 35 mm. The arched part may have a length ranging from about 40 mm to about 60 mm, preferably from about 45 mm to about 53 mm.

The arched part allows covering the various organs present in the medial inferior area of the inguinal region. In particular, the shape and dimension of the arched part allow spreading easily the prosthesis without having to tear it or to create specific folds in order to adapt to the unique anatomy of the patient to be treated.

In embodiments, the height of the arched part is greater or equal, preferably greater, than the height of the spherical cap of the first portion. The arched part is therefore allowed to cover the medial inferior area of the inguinal region while

the spherical cap conforms to the shape of the anterior abdominal wall, without having to apply any specific tension on the prosthesis in the front or rear directions.

In embodiments, said preformed three-dimensional shape defining an edge of said piece, said edge extends in the three dimensions of the space. The edge of the piece of biocompatible material follows the anatomy of the region to be protected in an optimum way. In particular, thanks to the fact that the edge of the piece extends in the three dimensions of the space, there is no need for the surgeon to create additional folds of the prosthesis in order to conform it to the anatomic shape to be protected.

In embodiments, said preformed three-dimensional shape defining an edge of said piece, said edge is provided with a reinforcement member at least on a part of its perimeter. The reinforcement member may be made from any biocompatible material and may run continuously or discontinuously along the edge. The reinforcement member may be selected from a moulded material, a wire, a fused textile part and combinations thereof. The reinforcement member is usually provided with a rigidity superior to that of the piece of biocompatible material and may help the handling of the prosthesis during the surgical operation.

In embodiments, the reinforcement member shows no elasticity along the perimeter of the edge. In other words, if one holds the piece at two points of its edge located substantially on a linear section of said edge, and tries to draw away one point from the other, the reinforcement member will show no elongation between the two points. The reinforcement member may therefore constitute a sort of three-dimensional non-elastic belt maintaining the edge of the piece of biocompatible material, where such belt provides a pop-up effect at the time the prosthesis comes out of a trocar for example. The reinforcement member therefore contributes to a more efficient deployment of the prosthesis when it comes out of the trocar.

In embodiments, the piece of biocompatible material may show an elasticity allowing it to be deformed when submitted to an outer pressure and to come back to its initial predetermined three-dimensional shape when said outer pressure is released. The surgeon may therefore be able to reduce the global volume of the prosthesis by applying an outer pressure on the prosthesis so as to fold it on itself at the time he introduces the prosthesis in the trocar. When the prosthesis is released from the trocar on the implantation site, namely in the inguinal region, the prosthesis comes naturally to its initial spread out three-dimensional shape.

A piece of biocompatible material showing such an elasticity may be made from a porous foam.

Alternatively, some textiles may form biocompatible material showing such an elasticity. A textile suitable for forming the piece of the prosthesis of the invention and showing an elasticity allowing it to be deformed when submitted to an outer pressure and to come back to its initial predetermined three-dimensional shape when said outer pressure is released is described in US 6, 478, 727. For example, such a textile may comprise a porous knit made of polypropylene monofilament yarn having a diameter ranging from about 0.12 mm to about 0.25 mm, preferably from about 0.15 mm to about 0.20 mm, for example of about 0.18 mm, and threaded one full one empty in two guide bars according to the following knitting pattern according to ISO 11676 standard, publication 2014 : Bar I : 3-2/2-1/0-1//, Bar II : 0-1/1-2/3-2//. For example, the number of stitches per centimeter for such a porous knit may vary from about 7 to 15, preferably from about 10 to 12.

In embodiments, the reinforcement member comprises a fused part of a contour of the textile forming the piece of biocompatible material. Alternatively, the reinforcement member may consist in a fused part of a contour of said textile. The fused part of the contour of a textile allows forming a reinforcement member having a smooth outer shape and free of any potential traumatic part. The fused part of the contour of a textile further allows forming a reinforcement member showing no elasticity along the perimeter of the edge. The fused part of the contour of the textile also allows avoiding the self-gripping of the textile.

The contour of the textile may be fused via thermal welding, such as thermal impulse sealing, ultrasonic welding, or induction welding. For example, when thermal impulse sealing is used, the contour of the textile is compressed between two jaws and heated to the melting point of the material forming the textile.

In embodiments, a medial inferior part of the edge is free of any reinforcement member. The absence of any reinforcement member at the medial inferior part of the edge of the piece of the prosthesis of the invention allows the surgeon to freely direct and position the medial inferior part of the prosthesis in function of the shape of the anatomical organs located in the area of the medial inferior area of the inguinal region. Indeed, it is known that the anatomy of the medial inferior area of the inguinal region varies significantly from one human being to the other. Leaving the medial inferior part of the prosthesis free of any reinforced edge enables the surgeon to adapt the positioning and to customize the fixation of the prosthesis in this area to the true shape of the anatomy encountered for a specific patient. The medial inferior part of the prosthesis is therefore more conformable to the anatomical relief encountered in the treated patient.

In embodiments, the piece of biocompatible material is a textile showing an elasticity allowing it to be deformed when submitted to an outer pressure and to come back to its initial predetermined three-dimensional shape when said outer pressure is released, having a reinforcement member which is a fused part of said textile, where the medial inferior part of the edge is free of any reinforcement member. Such embodiments allow having a non-elastic belt, formed by the reinforcement member, maintaining the prosthesis on the main part of its edge, while leaving the medial inferior part of the edge preserve its elasticity, coming from the elasticity of the textile it is made of. Such embodiments allow the surgeons to benefit from the elasticity of the medial inferior part of the edge of the textile in order to easily move the prosthesis in the medial inferior area of the inguinal region and to more freely adapt the position of the prosthesis to this specific part of the anatomy, while at the same time having a prosthesis that has enough global rigidity to be manipulated efficiently and to be spread out easily from the trocar.

In embodiments, the piece further includes a fourth portion extending from the superior-medial part of the first portion, said fourth portion forming a triangular part defining a superior-medial corner of the prosthesis, said corner forming an angle ranging from about 100° to about 120°, preferably from about 105° to about 115°, for example of about 110°. Such a fourth portion allows providing an indication to the surgeon for better positioning the prosthesis. In particular, such a fourth portion helps the surgeon to orientate the prosthesis with regards to the Linea Alba. In addition, the presence of the triangular part forming the fourth portion of the prosthesis allows increasing the surface of the prosthesis in the medial superior area of the inguinal region. Such embodiments are particularly preferred for direct inguinal hernia as they consequently provide additional reinforcement in said medial superior area.

The preformed three-dimensional shape of the prosthesis of the invention may be obtained using any preforming process known in the art, such as a compressive thermoforming process using a traditional two-parts mold. For example a first part of the mold exhibits an outer surface having the desired shape for the piece of the prosthesis to be obtained and a second part of the mold has a shape similar to that of the first part but recessed into its inner surface. The sheet of biocompatible material, for example a textile, is then secured between the first and the second parts of the mold, the whole being heated at a temperature ranging from about 140°C to about 150°C and further cooled down. The preformed three-dimensional shaped piece thus obtained is removed from the mold.

The present invention will become clearer from the following description and from the attached drawings, in which:

- Figure 1 is a schematic view of the inguinal region,
- Figure 2A is a top view of a first embodiment of a prosthesis of the invention,
- Figure 2B is a top view of a second embodiment of the prosthesis of the invention,
- Figure 3A is a side perspective view of the prosthesis of Figure 2A,
- Figure 3B is a cross section view of the prosthesis of Figure 3A taken along line I-I, showing the angle between the direction of the height of the spherical cap and the generatrix of the wavy-shaped wall,
- Figure 4 is a side view of the prosthesis of Figure 2A showing the radius of the arched part, the angle of the portion of a circle on which extends the arched part, and the height of the arched part,
- Figure 5 is a schematic top view of the first portion of the prosthesis of Figure 2A showing the radius of curvature of the curves of the wavy-shaped wall.

With reference to Figure 2A, is shown a prosthesis 1 of the invention for repairing a hernia defect in an inguinal region of the human body. The prosthesis 1 shown on Figure 1 is intended to be implanted in the left hand side of a patient body. The prosthesis 1 comprises a piece 2 of biocompatible material having a preformed three-dimensional shape. On Figure 2A are indicated the medial-lateral axis A and the superior-inferior axis B. The preformed piece 2 of Figure 2A has a lateral side 2a, a medial side 2b, a superior side 2c and an inferior side 2d. On Figure 2A is shown the front side of the prosthesis 1.

The piece 2 comprises a first portion 3, which is intended to face the anterior abdominal wall, a second portion 4, which is intended to face the psoas muscle and a third portion 5, which is intended to face the medial inferior area of the inguinal region. In the example shown the piece 2 further comprises a fourth portion 6, intended to ease the alignment of the prosthesis 1 on the Linea Alba. In embodiments not shown, the piece 2 does not comprise such fourth portion. The first portion 3, second portion 4, third portion 5 and fourth portion 6 are all united to form the preformed three-dimensional shaped piece 2 as a unitary structure. The piece 2 has an edge 7 defined by the contour of its preformed three-dimensional shape.

Each portion (3, 4, 5, 6) of the piece 2 of biocompatible material will now be described in detail.

The first portion 3 forms a partial spherical cap surface 8. The partial spherical cap surface 8 is intended to face the anterior abdominal wall once the prosthesis 1 is implanted in the body of a patient. The partial spherical cap surface 8 therefore extends in the front direction, namely towards the abdominal wall. The partial spherical cap surface 8 is shaped and dimensioned so as to conform to the curved shape of the anterior abdominal wall. The partial spherical cap surface 8 is further intended to be positioned adjacent the psoas muscle in an implanted configuration. In this view, the partial spherical cap surface 8 is derived from a spherical cap from which an inferior part has been removed, the inferior part removed corresponding to the presence of the psoas muscle. The partial spherical cap surface 8 may therefore be a spherical cap surface that has been cut in its inferior part along a line delimited by the shape of the psoas muscle. Such a line forms an inferior edge 8a of the partial spherical cap surface 8.

The spherical cap from which the first portion 3 is formed may be obtained from the cutting of a cap from a sphere having a diameter ranging from about 200 mm to about 220 mm, preferably ranging from about 206 mm to about 215 mm, where the cut cap has a height H, as shown on Figure 4, ranging from about 15 mm to about 35 mm, preferably from about 20 mm to about 28 mm. The partial spherical cap surface 8 forming the first portion 3 may result from the removal of an inferior part of such a spherical cap along a wavy line forming the inferior edge 8a of the partial spherical cap 8 and of the first portion 3.

The second portion 4 forms a wavy-shaped wall 9 intended to face the psoas muscle once the prosthesis 1 is implanted in the body of a patient. The wavy-shaped wall 9 extends from the inferior edge 8a of the first portion 3 and is shaped and dimensioned so as to conform to the shape of the psoas muscle.

With reference to Figure 2A, the wavy-shaped wall 9 extends from a lateral side 2a to substantially a medial side 2b of the piece 2. The wavy-shaped wall 9 includes a surface generated by a generatrix, under the form of a straight line D shown for example on Figures 3A and 3B, following a directrix, under the form of a directing curved line C shown for example on Figure 5. The wavy-shaped wall 9 may comprise a succession of several curves, for example two or three curves, forming a wave. In the example shown in Figure 2A, the wavy-shaped wall 9 comprises three curves, namely a lateral curve 9a extending substantially in the inferior direction, a central curve 9b extending substantially in the superior direction and a medial curve 9c extending in the inferior direction.

With reference to Figure 5, is shown a schematic top view of the first portion 3 of Figure 2A showing the directing curved line C including the lateral curve 9a, the central curve 9b and the medial curve 9c and their corresponding radius of curvatures (R1, R2, R3).

5 For example, the radius of curvature of the lateral curve 9a, shown as R1 on Figure 5, may range from about 50 mm to about 55 mm, and may preferably be about 53 mm, the radius of curvature of the central curve 9b, shown as R2 on Figure 5, may range from about 20 mm to about 35 mm, and may preferably be from about 24 mm to about 31 mm, and the radius of curvature of the medial curve 9c, shown as R3
10 on Figure 5, may range from about 70 mm to about 90 mm, and may preferably be about 80 mm.

The wavy-shaped wall 9 is inclined with respect to the direction of the height "h" of the spherical cap 8 of the first portion 3. With reference to Figure 3A and 3B, the angle α formed between the generatrix D of the wavy-shaped wall and the
15 direction "h" of the height of the spherical cap surface 8 of the first portion 3 may range from about 35° to about 50°, preferably from about 40° to about 45°.

With reference to Figure 2B, is shown a second embodiment of the prosthesis 1 of Figure 1, in which the wavy-shaped wall 9 does not comprise any medial curve. As will appear from the description below, the prosthesis of Figure 2B may be
20 designed for cases where the size of the hernia defect in the medial inferior area of the inguinal region requires high coverage from the prosthesis 1. The third portion 5 is made larger and replaces the medial curve of the wavy-shaped wall 9.

With reference to Figure 2A, the third portion 5 forms an arched part 10. The arched part 10 extends longitudinally substantially in the inferior direction from a
25 medial inferior corner 3a of the first portion 3. As better seen on Figure 4, the arched part 10 extends radially substantially in the front direction.

The arched part 10 forming the third portion 5 is intended to face the medial inferior area of the inguinal anatomy. The radius R4 of the arched part 10 is the radius of the tube from which the arched part derives and is shown in Figure 4.

30 The arched part 10 may have a radius R4 ranging from about 70 mm to about 110 mm, preferably from about 80 mm to about 100 mm.

With reference to Figure 4, the arched part 10 extends circumferentially along a portion of a circle forming an angle β ranging from about 30° to about 45°, preferably ranging from 33° to 40°.

35 Still with reference to Figure 4, the arched part 10 may have a height J ranging from about 20 mm to about 40 mm, preferably from about 21 mm to about 35

mm. With reference to Figures 2A and 2B, the arched part 10 may have a length L ranging from about 40 mm to about 60 mm, preferably from about 45 mm to about 53 mm.

5 The arched part 10 allows covering the various organs present in the medial inferior area of the inguinal region. In particular, the shape and dimension of the arched part 10 allow spreading easily the prosthesis 1 without having to tear it or to create specific folds in order to adapt to the unique anatomy of the patient to be treated.

10 Still with reference to Figure 4, the height J of the arched part 10 is greater than the height H of the spherical cap of the first portion 3. Once the prosthesis 1 is implanted, the arched part 10 is thus allowed to cover the medial inferior area of the inguinal region while the spherical cap surface 8 conforms to the shape of the anterior abdominal wall, without having to apply any specific tension on the prosthesis in the front or rear directions.

15 With reference to Figure 2A, the fourth portion 6 extends from the superior-medial part of the first portion 3. The fourth portion 3 forms a triangular part 12 defining a superior-medial corner of the prosthesis 1. For example, this corner may form an angle γ , as shown on Figure 2A, ranging from about 100° to about 120° , preferably from about 105° to about 115° , for example of about 110° . The triangular
20 part 12 allows the prosthesis 1 to provide an additional reinforcement in the medial superior area of the inguinal region. Such embodiments are particularly suitable when the hernia to be repaired is a direct inguinal hernia. The presence of the fourth portion 6 may also help the surgeon positioning optimally the prosthesis 1 by making the medial edge of the prosthesis 1 more visible to the surgeon. The surgeon may then more easily
25 align the medial edge of the prosthesis 1 with the Linea Alba.

With reference to Figure 4, one can see that the edge 7 extends in the three dimensions of the space. This allows the piece 2 to follow the anatomy of the region to be protected in an optimum way.

30 With reference to Figure 2A, the edge 7 is provided with a reinforcement member 11.

The reinforcement member 11 forms a non-elastic belt maintaining the prosthesis 1 and helps the handling of the prosthesis 1 while providing a pop-up effect when the prosthesis 1 has been folded on itself, like in a trocar for example.

35 On figure 2A, the reinforcement member 11 runs along a part of the edge 7 while leaving free the medial inferior part of said edge 7. In particular, the reinforcement member 11 runs from a first end 11a, approximately located at the level

of the central curve 9b, to a second end 11b, approximately located at the medial-inferior corner of the arched part 5, leaving free the medial inferior part of the edge 7. Such an embodiment, where the edge 7 is reinforced except in its medial inferior part, allows obtaining both the required pop-up effect for the deployment of the prosthesis 1 out of a trocar and the possibility to adapt and conform the third portion 5, namely the arched part 10, to the true anatomy of the medial inferior area of the inguinal region of the patient treated.

The four portions (3, 4, 5, 6) of the prosthesis 1 of Figure 2A are made from a biocompatible material. The biocompatible material may comprise a bioresorbable, a non-bioresorbable material and mixtures thereof.

The four portions (3, 4, 5, 6) of the prosthesis 1 of Figure 2A are preferably made from a porous textile, in particular a textile showing an elasticity allowing it to be deformed when submitted to an outer pressure and to come back to its initial predetermined three-dimensional shape when said outer pressure is released. Such a textile may for example be a porous knit made of polypropylene monofilament yarn having a diameter ranging from about 0.12 mm to about 0.25 mm, preferably from about 0.15 mm to about 0.20 mm, for example of about 0.18 mm, and threaded one full one empty in two guide bars according to the following knitting pattern according to ISO 11676 standard, publication 2014 : Bar I : 3-2/2-1/0-1//, Bar II : 0-1/1-2/3-2//. For example, the number of stitches per centimeter for such a porous knit may vary from about 7 to 15, preferably from about 10 to 12.

The reinforcement member 11 may be a fused part of the contour of the textile forming the piece 2, for example obtained by thermal welding. Such a fused part shows a smooth outer shape and is free of any traumatic element. Such a fused part also allows avoiding self-gripping of the textile when the prosthesis is folded on itself during its introduction to the implantation site via a trocar.

When the textile is a porous knit obtained from polypropylene monofilament as described above, the reinforcement member may be obtained by fusing the contour of the textile as follows : the contour of the textile is compressed between two jaws and heated to about 240°C which is the melting point of polypropylene.

The piece 2 of the prosthesis 1 may be obtained using a compressive thermoforming process : for example a flat textile such as the textile described above is secured between the two parts of a mold having the desired shape for the piece of the prosthesis to be obtained. The whole is heated at temperature of about 140 °C and then cooled down in order to obtain the preformed three-dimensional shaped piece 2.

The preformed three-dimensional shaped piece thus obtained from said textile shows an elasticity allowing it to be deformed when submitted to an outer pressure and to come back to its initial predetermined three-dimensional shape when said outer pressure is released. Fusing the edge of the piece except for the medial inferior part of the edge allows forming a prosthesis capable of spreading out automatically from a trocar and having a good handleability, while showing in its medial inferior part an elasticity enabling the surgeon to conform the prosthesis to the medial inferior area of the inguinal region of the patient being treated.

The prosthesis of the invention is adapted to be used in the repair of inguinal hernia, such as the direct inguinal hernia, the indirect inguinal hernia and/or the femoral inguinal hernia. In particular, the prosthesis of the invention allows covering the medial inferior area of the inguinal anatomy, in particular the region around the upper part of the pubic bone, without having to tear or stretch the other parts of the prosthesis or to create additional folds likely to undesirably interfere with the surrounding organs.

CLAIMS

1. An implantable prosthesis (1) for repairing a hernia defect in an inguinal region of a human body delimited by the anterior abdominal wall, the psoas muscle and a medial inferior area of the inguinal anatomy, the prosthesis comprising :

5 a piece (2) of biocompatible material having a preformed three-dimensional shape, the piece including :

- a first portion (3) , intended to face the anterior abdominal wall, said first portion forming a partial spherical cap surface (8) shaped and dimensioned so as to substantially conform to the shape of the anterior abdominal wall,
- a second portion (4), intended to face the psoas muscle, said second portion extending from an inferior edge of said first portion and forming a wavy-shaped wall (9), shaped and dimensioned so as to substantially conform to the shape of the psoas muscle,

15 characterized in that said piece (2) further comprises :

- a third portion (5) forming an arched part (10), said arched part extending longitudinally substantially in the inferior direction from a medial inferior corner (3a) of said first portion, said arched part extending radially substantially in the front direction, said third portion being intended to face the medial inferior area of the inguinal anatomy.

2. The prosthesis (1) of claim 1, wherein said preformed three-dimensional shape defining an edge (7) of said piece, said edge extends in the three dimensions of the space.

25 3. The prosthesis (1) of claim 1 or 2, wherein said preformed three-dimensional shape defining an edge (7) of said piece, said edge is provided with a reinforcement member (11) at least on a part of its perimeter.

4. The prosthesis (1) of claim 3, wherein a medial inferior part of the edge (7) is free of any reinforcement member (11).

30 5. The prosthesis (1) of any one of claims 1-4, wherein the piece (2) of biocompatible material comprises a textile.

6. The prosthesis (1) of claim 5, wherein the reinforcement member (11) comprises a fused part of a contour of said textile.

35 7. The prosthesis (1) of any one of claims 3-6, wherein said reinforcement member shows no elasticity along the perimeter of the edge.

8. The prosthesis (1) of any one of claims 1-7, wherein the piece (2) of biocompatible material shows an elasticity allowing it to be deformed when submitted to an outer pressure and to come back to its initial predetermined three-dimensional shape when said outer pressure is released.

5 9. The prosthesis (1) of any one of claims 1-8, wherein the spherical cap of said first portion (3) derives from a sphere having a diameter ranging from about 200 mm to about 220 mm, preferably ranging from about 206 mm to about 215 mm, said spherical cap having a height (H) ranging from about 15 mm to about 35 mm, preferably from about 20 mm to about 28 mm.

10 10. The prosthesis (1) of any one of claims 1 to 9, wherein said wavy-shaped wall (9) extending substantially from a lateral side to a medial side of the piece (2), said wavy-shaped wall includes a surface generated by a generatrix, under the form of a straight line D, following a directrix, under the form of a directing curved line C.

15 11. The prosthesis of claim 10, wherein said directing curved line C includes at least a lateral curve (9a) extending substantially in the inferior direction and at least a central curve (9b), offset in the medial direction with respect to said lateral curve, said central curve extending substantially in the superior direction.

20 12. The prosthesis (1) of claim 11, wherein the radius of curvature (R1) of the lateral curve (9a) ranges from about 50 mm to about 55 mm, is preferably about 53 mm, the radius of curvature (R2) of the central curve (9b) ranges from about 20 mm to about 35 mm, preferably ranges from about 24 mm to about 31 mm.

 13. The prosthesis of claim 11 or 12, wherein the directing curved line C further includes a medial curve (9c) extending in the inferior direction.

25 14. The prosthesis of claim 13, wherein the radius of curvature (R3) of the medial curve (9c) ranges from about 70 mm to about 90 mm, is preferably about 80 mm.

30 15. The prosthesis (1) of any one of claims 10-14, wherein the angle (α) formed between the generatrix (D) of the wavy-shaped wall and the direction "h" of the height of the spherical cap of the first portion (3) ranges from about 35° to about 50°, preferably from about 40° to about 45°.

 16. The prosthesis (1) of any one of claims 1-15, wherein the arched part (10) has a radius (R4) ranging from about 70 mm to about 110 mm, preferably from about 80 mm to about 100 mm.

35 17. The prosthesis (1) of any one of claims 1-16, wherein the arched part (10) extends circumferentially along a portion of a circle forming an angle (β) ranging from about 30° to about 45°, preferably ranging from 33° to 40°.

18. The prosthesis (1) of any one of claims 1-17, wherein the arched part (10) has a height (J) ranging from about 20 mm to about 40 mm, preferably from about 21 mm to about 35 mm.

5 19. The prosthesis (1) of any one of claims 1-18, wherein the arched part (10) has a length (L) ranging from about 40 mm to about 60 mm, preferably from about 45 mm to about 53 mm.

20. The prosthesis (1) of any one of claims 1-19, wherein the piece (2) further includes a fourth portion (6) extending from the superior-medial part of the first portion, said fourth portion forming a triangular part (12) defining a superior-medial
10 corner of the prosthesis, said corner forming an angle (γ) ranging from about 100° to about 120°, preferably from about 105° to about 115°, for example of about 110°.

21. The prosthesis (1) of claims 9 and 18, wherein the height (J) of the arched part (10) is greater or equal, preferably greater, than the height (H) of the spherical cap of the first portion (3).

15

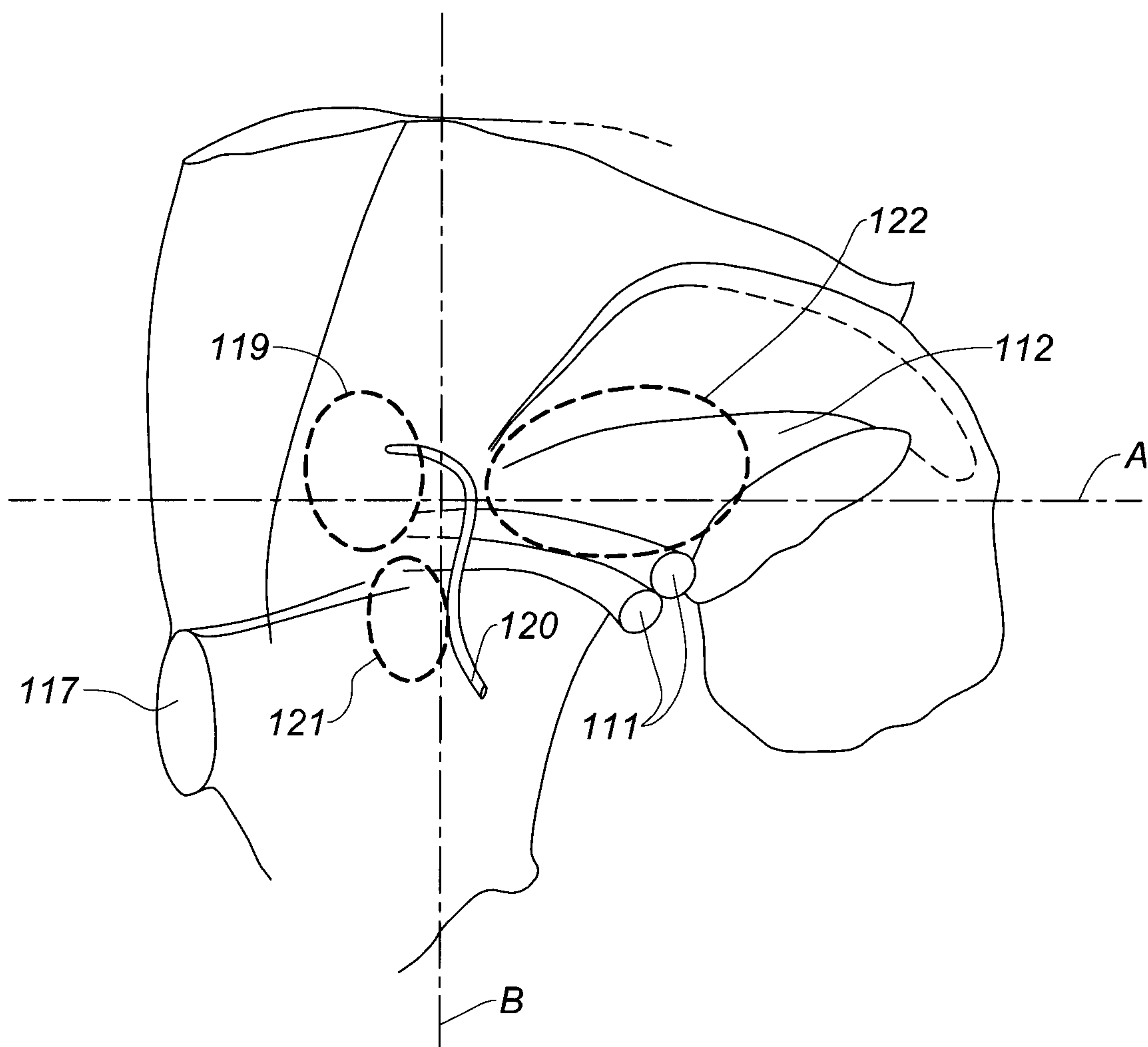


Fig. 1

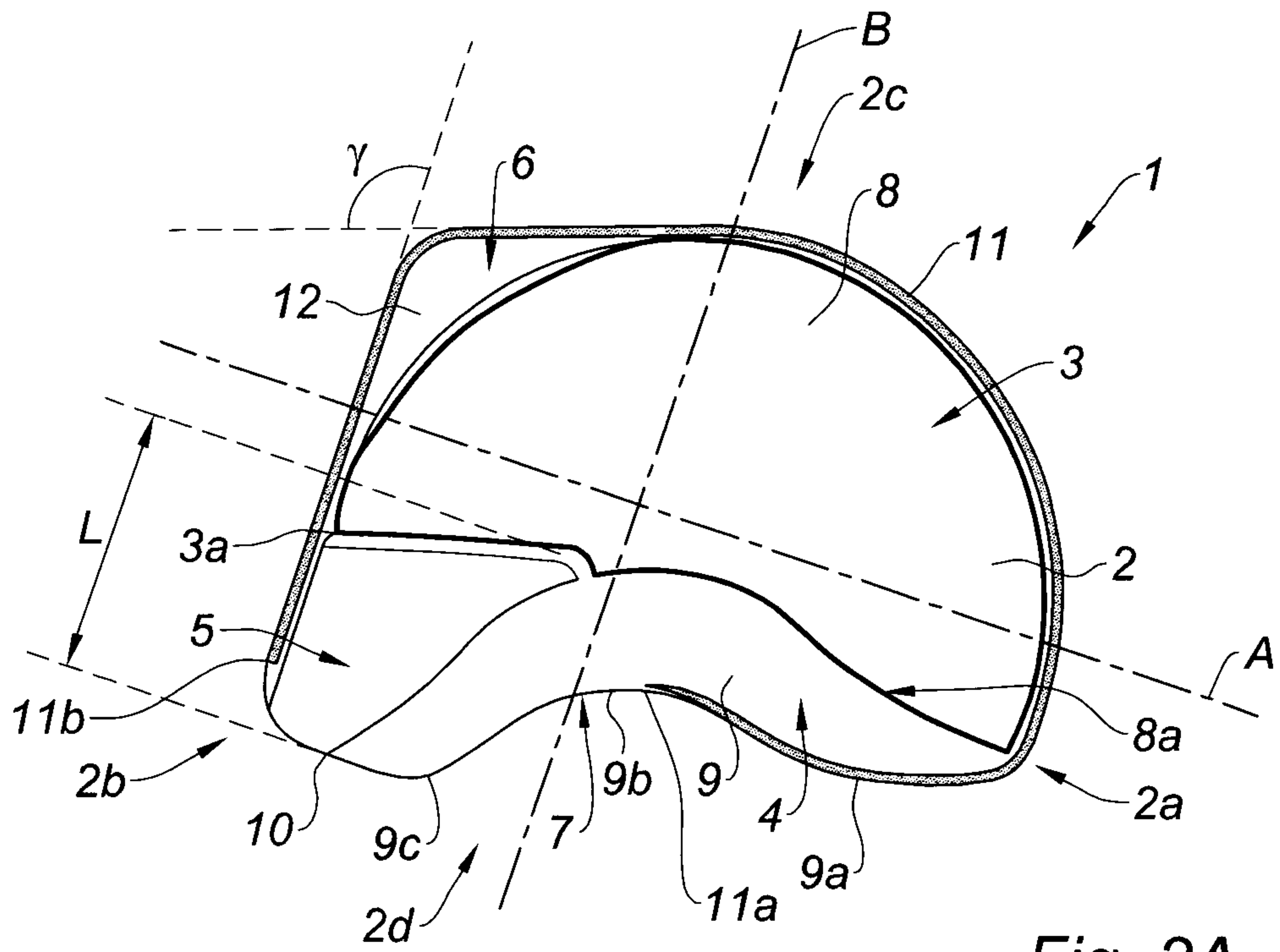


Fig. 2A

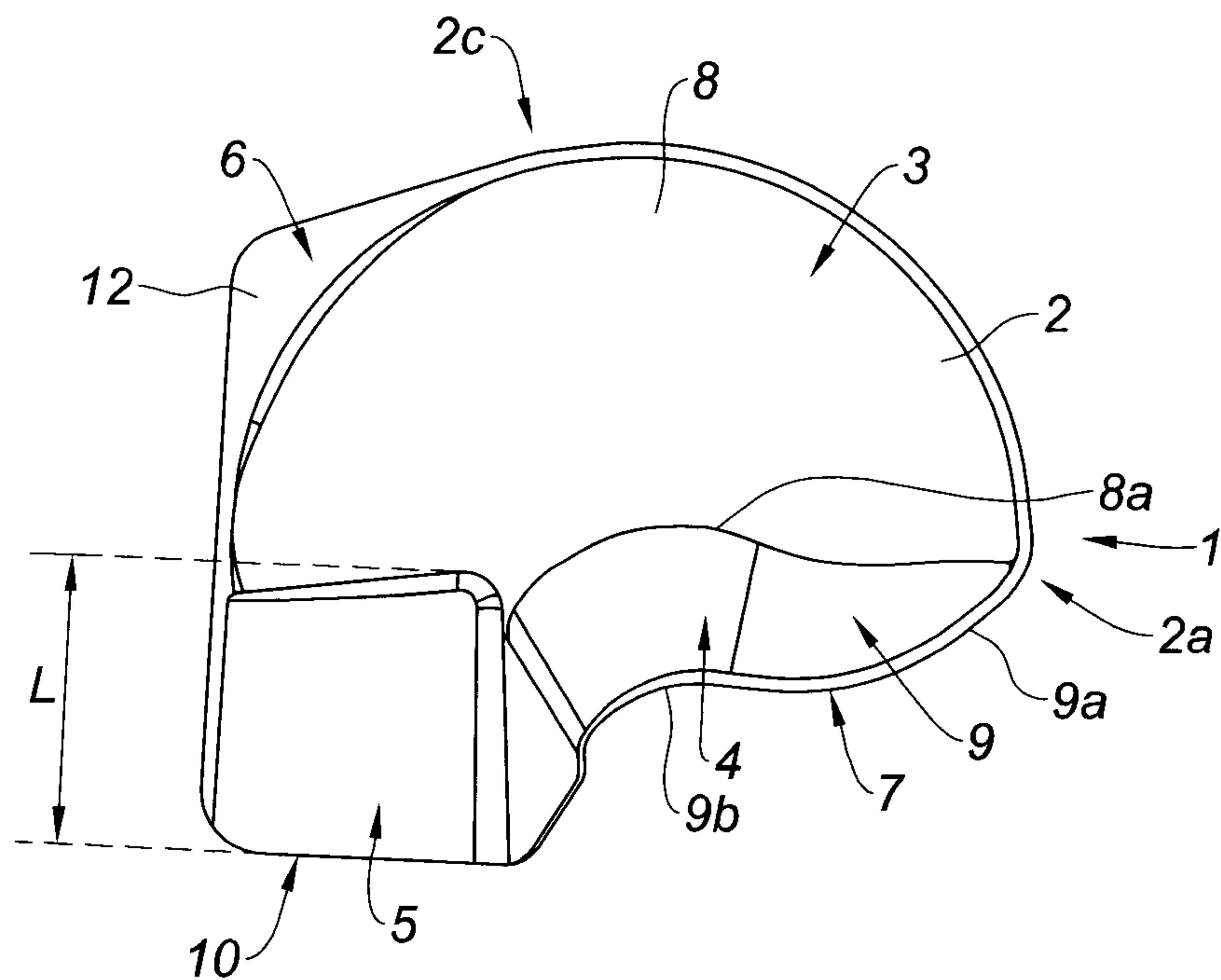


Fig. 2B

3 / 4

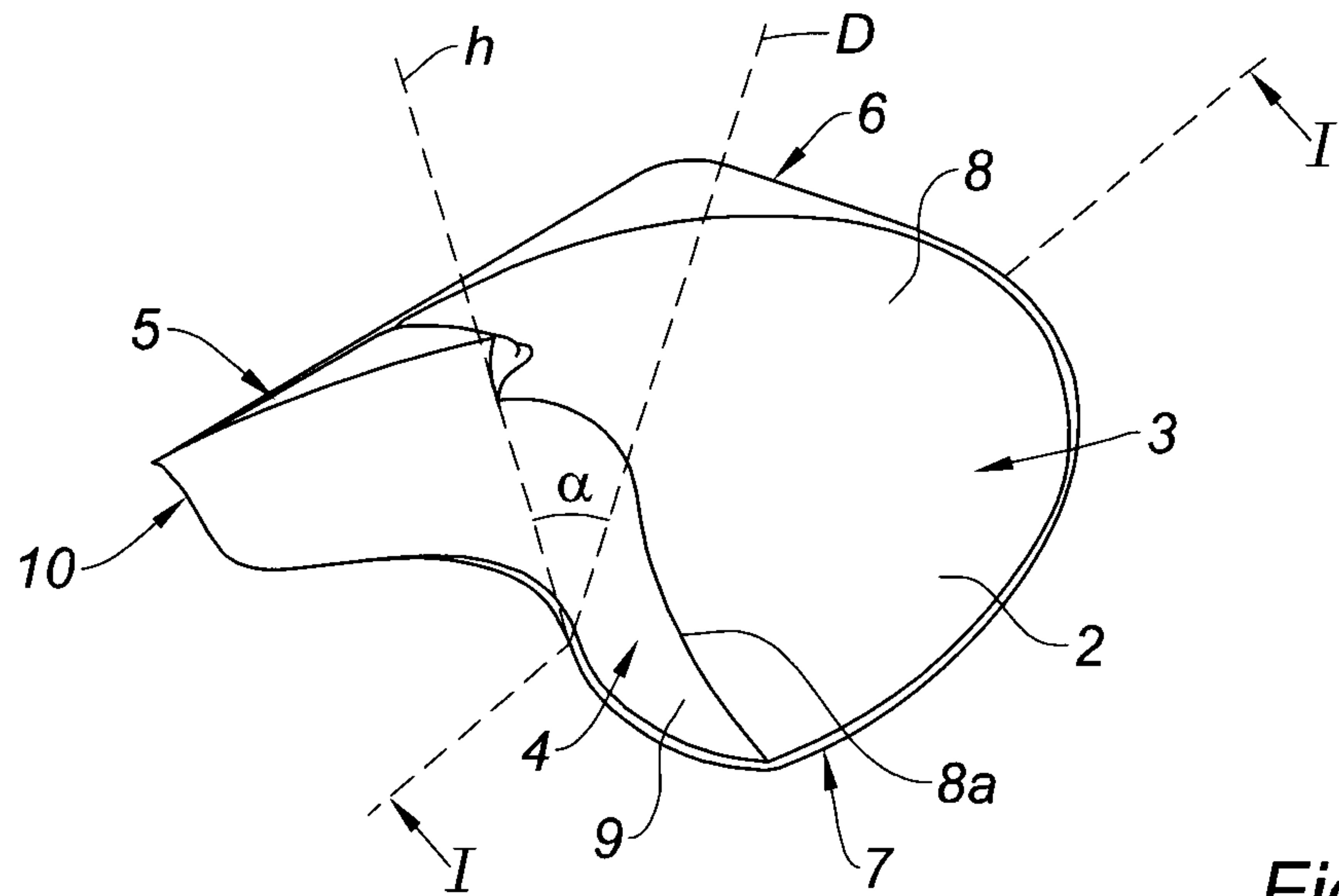


Fig. 3A

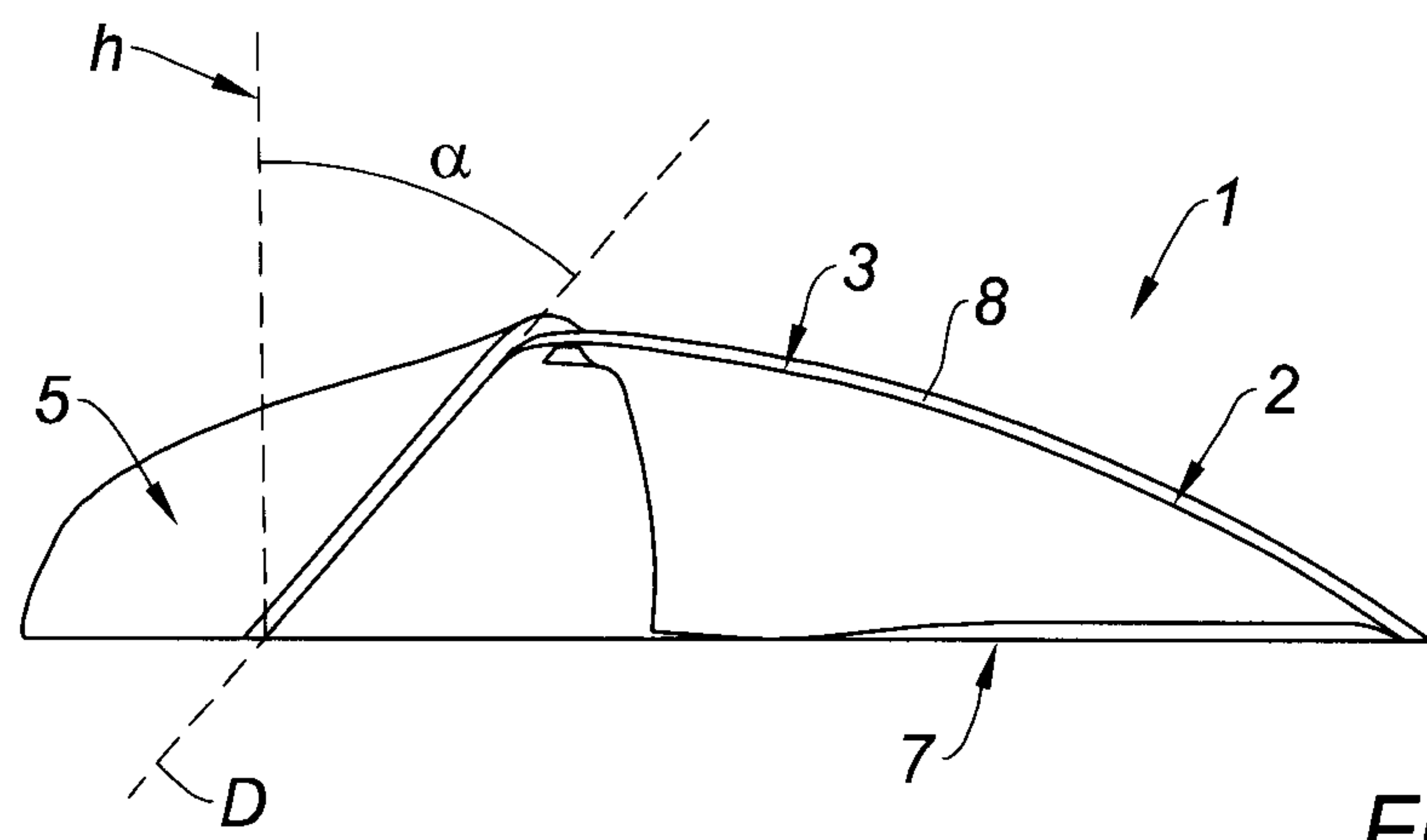


Fig. 3B

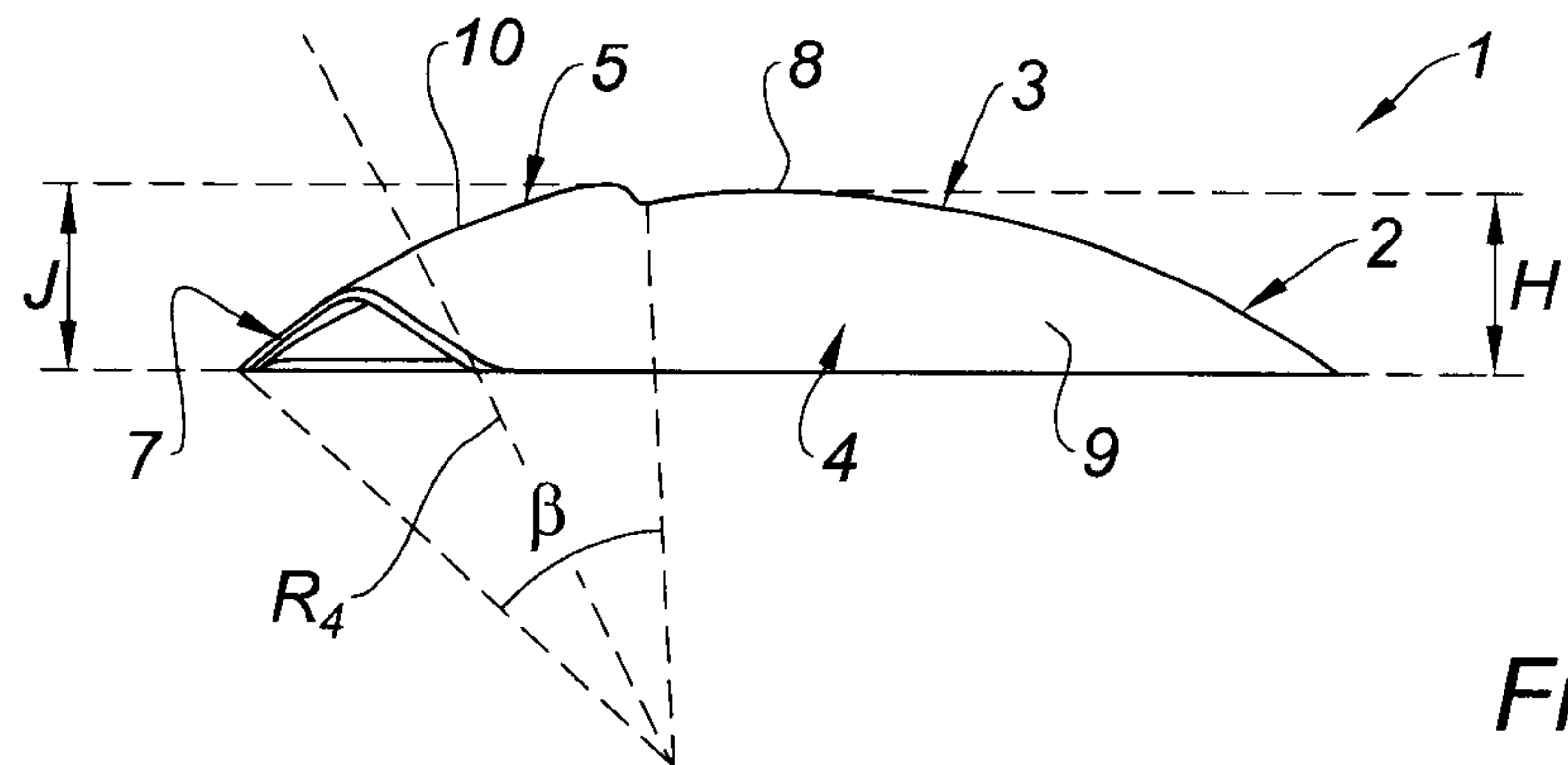


Fig. 4

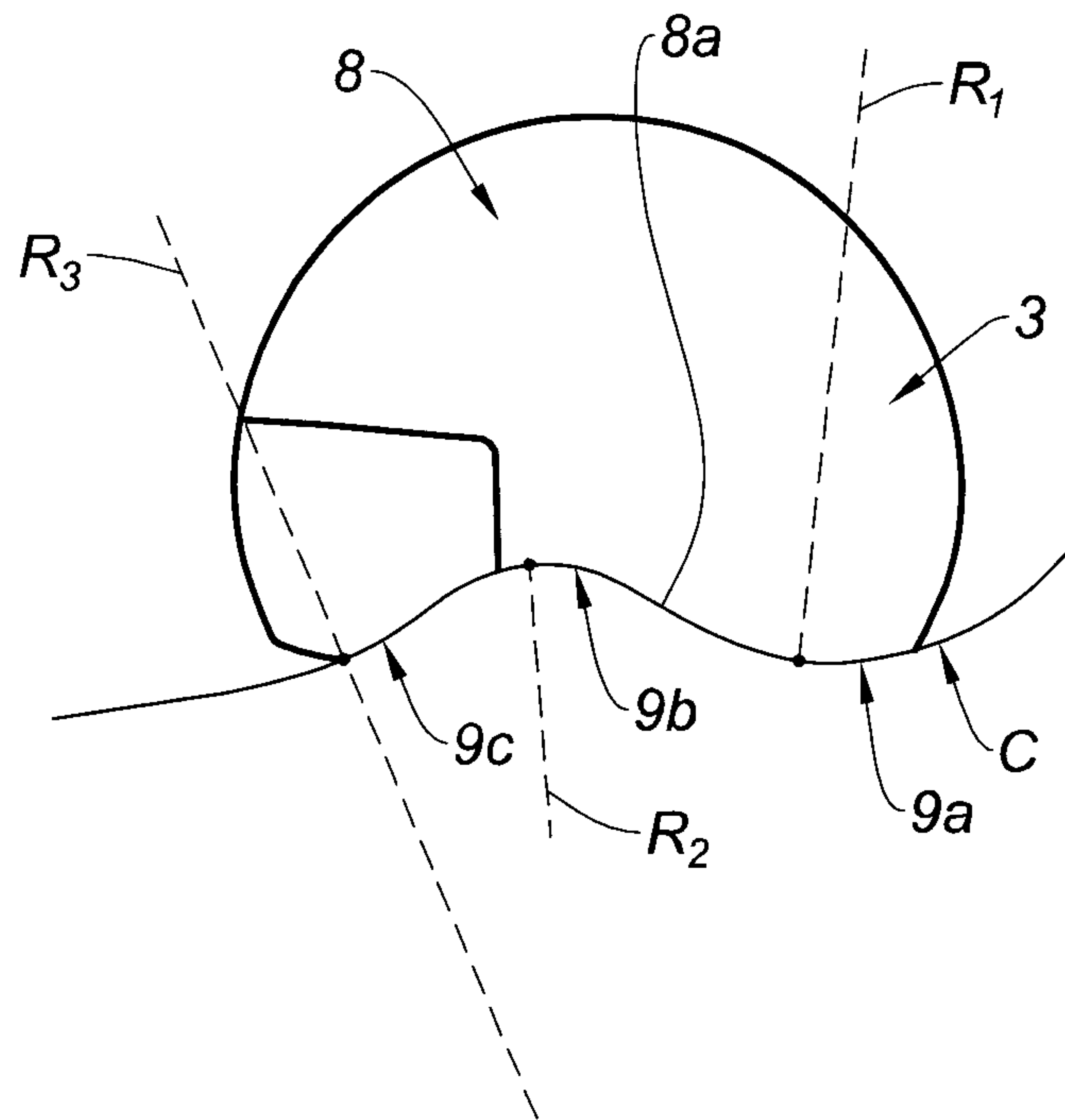


Fig. 5

