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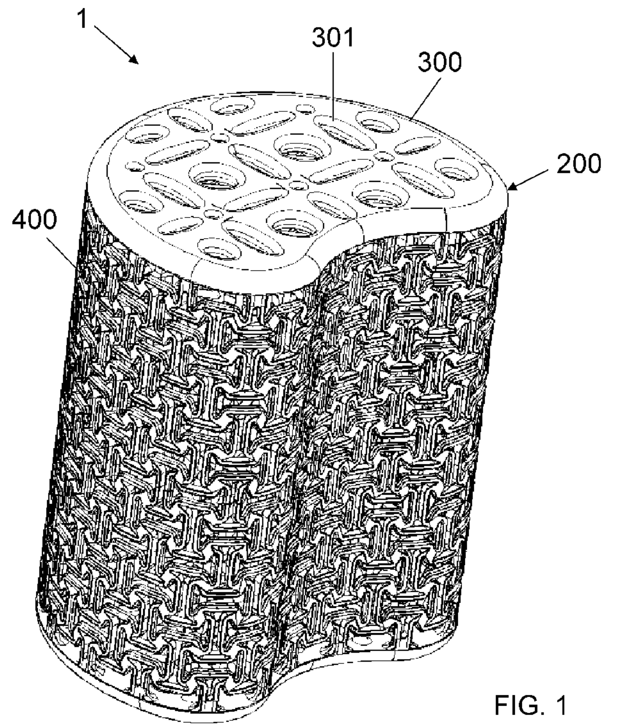

FIG. 1

(57) **Abstract:** Vertebral prosthesis (1), intended to be mechanically connected to a user's spinal column, comprising at least one containment structure (200), comprising at least two bases (300) spaced apart from each other and at least one lateral wall (400) mechanically connected to said at least two bases (300) said at least two bases (300) at their perimeter edges; at least one supporting structure (500) housed in said containment structure (200) between said two bases (300); said supporting structure (500) is made with an auxetic metamaterial comprising at least one operating cell (2) equipped with a negative Poisson coefficient.

WO 2024/180478 A1

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VERTEBRAL PROSTHESIS

DESCRIPTION

TECHNICAL FIELD

The present invention refers to a vertebral prosthesis, i.e. a device designed to replace (by means of a surgical operation) one or more components of a patient's spinal column and configured to guarantee correct alignment of the spine and at the same time ensuring mechanical stability of the column itself.

Therefore, the vertebral prosthesis in question finds advantageous use in the healthcare sector and in particular in the orthopedic sector of installation and use of prostheses, in particular for parts or components of the spinal column.

Furthermore, the vertebral prosthesis in question is also advantageously used in the technical sector of production and marketing of healthcare items, in particular prosthetic healthcare items, preferably custom made for each patient and user.

PRIOR ART

In the orthopedic sector, the use of prostheses for the replacement of damaged parts or components, for example bones, cartilage, joints or similar, has long been known. More in detail, the use of appropriate artificial devices configured to replace a missing body part (bones, joints, a limb, an organ or a tissue, etc.), or to integrate a damaged part to improve its functionality, is known.

In recent years, the need to develop prosthetic devices for the replacement of parts of damaged spinal columns of patients has been particularly felt. As it is known, the spinal column is a complex bone structure, capable not only of carrying out the mechanical function of maintaining an upright posture, but also of neuronal passage of the spinal cord to which all the nerves of the human body are connected.

In this situation, the development and installation of vertebral prostheses is complex and expensive.

Current prostheses involve the creation of metal reticular scaffolds, in particular made by 3D printing, with dimensions and shape similar to those of the part to be replaced.

Great difficulty in the creation of vertebral prostheses lies in providing the prosthesis with the correct mechanical features, in particular the correct stiffness. In fact, an excessively compliant vertebral prosthesis brings the intrinsic drawback of not being able to counterbalance mechanical efforts, for example compression, shifting this effort onto the adjacent bones, which incur premature impoverishment.

Likewise, a vertebral prosthesis that is too rigid incurs the inconvenience of absorbing a large part of the mechanical forces of the entire spinal column, leading the adjacent bones to weaken as they are not subject to the correct mechanical stress.

Over the years, these drawbacks have been addressed by changing the type of material used, for example by switching to biocompatible and light metals such as titanium or biocompatible polymers and/or composites.

However, to date in the relevant technical sector there are no vertebral prostheses that are equipped with the correct mechanical characteristics and at the same time are biocompatible, i.e. that it is a material (not of biological origin) compatible with the fluids and tissues of the receiving organism.

A further drawback lies in the fact that known prostheses are equipped with low porosity, wherein this low porosity value makes these prostheses poorly engageable with the bones and tissues of the spinal column.

SCOPE OF THE INVENTION

The scope of the present invention is to provide a vertebral prosthesis which allows to obviate and remedy, at least in part, the drawbacks of the above-mentioned known technique.

A further object of the present invention is to provide a vertebral prosthesis which is equipped with high porosity, for example a porosity greater than 70%.

A further scope of the present invention is to provide a vertebral prosthesis which has a stiffness very similar to that of the natural vertebra.

A further scope of the present invention is to provide a vertebral prosthesis that is light and resistant.

A further scope of the present invention is to provide a vertebral prosthesis which is functionally and structurally completely safe and reliable.

A further scope of the present invention is to provide a vertebral prosthesis which can be manufactured simply, quickly and at low costs.

A further scope of the present invention is to provide a vertebral prosthesis that can be made of any material, for example titanium or polymers, with good elastic deformability regardless of the material used.

A further scope of the present invention is to provide a vertebral prosthesis that can be made in the most appropriate dimensions for the clinical case under consideration.

SUMMARY OF THE INVENTION

All the scopes, both individually and in any combination thereof, and others that will result from the detailed description that follows are achieved, according to the invention, with a vertebral prosthesis having the features indicated in independent claim 1.

In particular, the aforementioned scopes are achieved with a vertebral prosthesis 1 intended to be mechanically connected to a user's spinal column, comprising at least one containment structure 200, comprising at least two bases 300 spaced apart from each other and at least one lateral wall 400 mechanically connected to said at least two bases 300 at their perimeter edges; at least one supporting structure 500 housed in said containment structure 200 between said two bases 300.

Said supporting structure 500 is made with an auxetic metamaterial comprising at least one operating cell 2 having a negative Poisson coefficient.

Advantageously, said operating cell 2 of said supporting structure 500 comprises a plurality of elementary bodies 3 that are congruent with each other and mechanically connected; each of said elementary bodies 3 has a substantially prismatic shape with a triangular base; said elementary bodies 3 are connected to each other at respective vertices 31, 32 by means of elastically yielding connection means 4.

Advantageously, said supporting structure 500 is mechanically connected to said bases 300.

Advantageously, said supporting structure 500 is mechanically disengaged from said lateral wall 400 and defines an annular chamber 450 with said lateral wall 400.

Advantageously, each of said elementary bodies 3 of said supporting structure 500 is a reticular body comprising:

- at least a first a first triangular-shaped base defined by three first elongated elements 5 mechanically connected to each other in a triangle at three first vertices 31;
- at least a second triangular-shaped base, arranged facing said first base, defined by three second elongated elements 6 mechanically connected to each other in a triangle at three second vertices 32;
- lateral elongated elements 7 placed to connect said first vertices 31 with said second vertices 32.

Advantageously, each of said elementary bodies 3 of said supporting structure 500 includes three first vertices and three second vertices; and by the fact that each of said elementary bodies 3 includes elongated elements 5, 6, 7 placed to connect between said first vertices 31 and/or said second vertices 32.

Advantageously, said elementary bodies 3 are configured to rotate on said elastically yielding connection means 4 following the application of an external force.

Advantageously, said lateral wall 400 is made with an auxetic metamaterial comprising at least one elementary structure 51 having a negative Poisson's coefficient.

Advantageously, said elementary structure 51 develops mainly planarly and includes a central body 52, four ligaments 53a, 53b, 53c, 53d developing starting from said central body 30 and capable of each connecting said elementary structure 51 with adjacent elementary structures 51.

Advantageously, said vertebral prosthesis develops along a main X axis with a substantially constant cross-section and a substantially concave shape.

BRIEF DESCRIPTION OF THE FIGURES

The present invention is further clarified below in some of its preferred practical embodiments, reported for purely illustrative and non-limiting purposes, with reference to the attached figures, wherein:

- Figure 1 shows a perspective view of the vertebral prosthesis according to the present invention;
- Figure 2 shows a further perspective view of the vertebral prosthesis which is the subject of the invention;
- Figure 3 shows a perspective view in longitudinal section of the vertebral prosthesis of figures 1 and 2;
- Figure 4 shows a perspective view of a detail of the vertebral prosthesis, concerning a lateral wall of one of its containment structures;
- Figure 5 shows a detailed front view of the lateral wall illustrated in figure 4;
- Figure 5b shows a detail in front view of the lateral wall of figure 5;
- Figure 5c shows a further detail of the lateral wall illustrated in figure 5b, created according to line C;

- Figure 6 shows a cross-section view of the lateral wall of the containment structure;
- Figure 7 shows a longitudinal and transversal section perspective view of the vertebral prosthesis according to the invention;
- Figure 8 shows a detailed front view of the section illustrated in figure 6;
- Figure 9 shows a perspective view of a detail of a supporting structure of the prosthesis according to the invention, concerning an elementary body of an auxetic metamaterial that makes up the supporting structure;
- Figure 10 shows a further perspective view of the elementary body of the auxetic metamaterial illustrated in figure 9;
- Figure 11 shows a perspective view of the elementary body of the auxetic metamaterial illustrated in figure 9;
- Figure 12 shows a further perspective view of the elementary body of the auxetic metamaterial illustrated in figure 10;
- Figure 13 shows a perspective view of a further detail of the auxetic metamaterial of the supporting structure, concerning an operational cell of the auxetic metamaterial, comprising a plurality of elementary bodies connected to each other;
- Figure 14 shows a front view of the operating cell illustrated in figure 13.

DETAILED DESCRIPTION OF THE INVENTION

With reference to the attached figures, with 1 is indicated as a whole a vertebral prosthesis, the object of the present invention.

The object of the present invention is a vertebral prosthesis 1, which is advantageously intended to be mechanically connected to a user's spinal column, comprising at least one containment structure 200, comprising at least two bases 300 spaced apart from each other and at least one lateral wall 400 mechanically connected to said at least two bases 300 at their perimeter edges; at least one supporting structure 500 housed in said containment structure 200 between said two bases 300.

Said supporting structure 500 is made with an auxetic metamaterial comprising at least one operating cell 2 having a negative Poisson coefficient.

Advantageously, in accordance with the preferential but non-limiting embodiment illustrated in the attached figures 9-14, said operating cell 2 of said supporting structure 500 comprises a plurality of elementary bodies 3 which are congruent and mechanically connected; each of said elementary bodies 3 has a substantially prismatic shape with a triangular base; said elementary bodies 3 are connected to each other at respective vertices 31, 32 by means of elastically yielding connection means 4.

Advantageously, said supporting structure 500 is mechanically connected to said bases 300.

The bases 300 are preferably configured to mechanically connect the lateral wall 400 with the supporting structure 500. More in detail, the supporting structure 500 is connected at the ends to the bases 300, which in turn are connected peripherally to the lateral wall.

The bases 300 are also configured to define - once installed in the spinal column of a patient - a contact surface (preferably stable) between the prosthesis according to the invention and the healthy contiguous bones of the spinal column.

In more detail, each base 300 includes a plate with a thickness between 1 and 2 mm. Furthermore, each base 300 preferably has a shape substantially equal to the cross section of the lateral wall 400. Preferably, the shape of the bases 300 is similar to that of human vertebral bones, in particular of the lumbar type.

Preferably, each base 300 has a plurality of holes 301, which can have different shapes. For example, the holes 301 of each base 300 can have a substantially circular shape 310', in particular with a larger diameter of approximately 0.5 mm, and an elliptical shape (301''), in particular with a larger diameter of approximately 0.7 mm.

These holes 301 are through and preferably made on the entire surface of the bases 300, except for the perimeter edge, mechanically fixed to the lateral wall 400.

The holes 301 advantageously allow to increase the phenomenon of bone regrowth inside the vertebral prosthesis 1, favoring a greater diffusion of the organic substances inside the prosthesis 1 itself.

Advantageously, said supporting structure 500 is mechanically disengaged from said lateral wall 400 and defines an annular chamber 450 with said lateral wall 400.

Advantageously, each of said elementary bodies 3 of said load-bearing structure 500 is a reticular body comprising:

- at least a first a first triangular-shaped base defined by three first elongated elements 5 mechanically connected to each other in a triangle at three first vertices 31;
- at least a second triangular-shaped base, arranged facing said first base, defined by three second elongated elements 6 mechanically connected to each other in a triangle at three second vertices 32;
- lateral elongated elements 7 placed to connect said first vertices 31 with said second vertices 32.

Advantageously, each of said elementary bodies 3 of said supporting structure 500 includes three first vertices and three second vertices; and by the fact that each of said elementary bodies 3 includes elongated elements 5, 6, 7 placed to connect between said first vertices 31 and/or said second vertices 32.

Advantageously, said elementary bodies 3 are configured to rotate on said elastically yielding connection means 4 following the application of an external force.

Advantageously, said lateral wall 400 is made with an auxetic metamaterial comprising at least one elementary structure 51 having a negative Poisson's coefficient.

Advantageously, said elementary structure 51 develops mainly planar and comprises a central body 52, four ligaments 53a, 53b, 53c, 53d extending from said central body 52 and able of each connecting said elementary structure 51 with contiguous elementary structures 51.

Advantageously, said vertebral prosthesis develops along a main X axis with a substantially constant cross section, in particular with a substantially concave shape.

Conveniently, the term "metamaterial" shall mean, pursuant to this patent, an artificial material whose structure is designed to provide special mechanical properties not normally found in natural materials and, in particular, not present in individual materials, when taken alone, which define it.

The metamaterial in question has auxetic behavior, i.e. It has a negative Poisson's ratio. In particular, the Poisson ratio is a dimensionless quantity and represents the degree to which the material sample shrinks or expands transversally in the presence of a longitudinal monodirectional stress. In particular, auxetic materials, if subjected to a monodirectional longitudinal stress, behave in the opposite way compared to other materials: if the stress is tensile, the auxetic material expands in a transverse direction with respect to the stress, while if the stress is compressive, the auxetic material shrinks in the transverse direction with respect to the stress.

This mechanical behavior of the auxetic metamaterial in question is due to its construction geometry and not to the material of which it is composed (if not to a minimal extent).

Advantageously, the auxetic metamaterial in question finds advantageous use in the technical sector of production and marketing of prostheses, in particular bone or vertebral prostheses. In fact, as will be clear from the following description, the metamaterial according to the invention is suitable for achieving mechanical characteristics similar to those of human bone tissue.

Obviously, the auxetic metamaterial in question can be used for the production of any type of product that requires the aforementioned auxetic behavior, without thereby leaving the scope of protection of this patent.

Preferably, the auxetic metamaterial according to the invention is made by additive manufacturing, in particular by three-dimensional printing and more preferably by three-dimensional printing of the SLM (Selective Laser Melting) type.

The auxetic metamaterial in question can advantageously be made of metallic material, such as for example titanium, or of plastic material, for example Onyx or similar, or even of composite material. For the purpose of making bone or vertebral prostheses, the auxetic metamaterial is made of biocompatible material, for example titanium or an alloy thereof, for example a titanium alloy with aluminium-vanadium, in particular Ti6Al4V ELI.

The auxetic metamaterial of the supporting structure 500 of the vertebral prosthesis 1 comprising at least one operating cell 2 having a negative Poisson's coefficient.

For the purposes of this patent, "operational cell" must be understood as a basic structure (preferably reticular, as described in detail below) capable of being reproduced identical to itself in three dimensions and having an auxetic behavior, i.e. with a negative Poisson's ratio.

The operational cell 2 includes a plurality of elementary bodies 3 that are congruent with each other and mechanically connected, wherein each of said elementary bodies 3 has a substantially prismatic shape with a triangular base.

The term "elementary body" must be understood for the purposes of this patent as a body, preferably rigid, intended to be mechanically connected to other elementary bodies to form a three-dimensional structure. Conveniently, pursuant to this patent, an operational cell 2 comprises eight elementary bodies 3 mechanically connected to each other.

Conveniently, the elementary bodies 3 are connected to each other at respective vertices 31, 32 by elastically yielding connection means 4.

Preferably, the supporting structure 500 is connected to the bases 300 by means of the elastically yielding connection means 4.

In this way, the auxetic metamaterial object of the present invention allows to obtain great flexibility, high auxetic behavior and, at the same time, a geometry that is easy to produce, preferably through three-dimensional molding.

Advantageously, said operating cell 2 comprises eight said elementary bodies 3 mechanically connected to each other.

In accordance with the preferential embodiment of the present invention illustrated in the attached figures, the operating cell 2 includes eight elementary bodies 3 connected by defining two superimposed planes, wherein a first plane defined by four elementary bodies 3 and a second plane arranged alongside the first defined by a further four elementary bodies 3.

Preferably, each said elementary body 3 is rotated and mirrored with respect to each said elementary body 3 adjacent to it.

Advantageously, with particular reference to the attached figures 9-14, according to the present description a reference system of the auxetic metamaterial of the supporting structure 500 is defined, wherein an axis X passes through an edge (i.e. edge) of a triangular base of the elementary body 3 of prismatic shape, an axis Y is orthogonal to the axis X and orthogonal to the plane on which the triangular base lies and an axis Z is orthogonal to both the X and Y axes.

In the same way, with particular reference to the attached figures 9-12, a reference system of the elementary body is defined, wherein an axis Xc is passing through an edge (i.e. a rim) of a triangular basis of the elementary body of prismatic shape, and an axis Yc is orthogonal to the axis Xc as well as parallel to the lateral bodies 7 and orthogonal to the plane on which the triangular base lies and an axis Zc is orthogonal to both Xc and Yc axes.

Preferably, with reference to the attached figures 13, 14 which show an operating cell 2 of the auxetic metamaterial respectively in axonometry and in a lateral view, each elementary body 3 is symmetrical (and mirrored) with respect to each contiguous elementary body 3.

For example, with reference to the attached figure 14, each of the elementary bodies 3 depicted are symmetrical to the adjacent elementary bodies 3 with respect to axes of symmetry X' and Y' parallel to the X and Y axes respectively.

Similarly, each elementary body 3 is symmetrical with respect to the adjacent elementary body 3, with respect to a symmetry axis Z' parallel to the Z axis and/or with respect to a symmetry axis X' parallel to the X axis.

Conveniently, the axes of symmetry pass through the connection means 4, in particular configured to mechanically connect in an elastically yielding manner the vertices 31, 32 of each elementary body 3 with the adjacent elementary bodies 3.

Preferably, in order to increase the porosity of the auxetic metamaterial according to the present invention, each of said elementary bodies 3 is a reticular body.

The term "reticular body" refers to a body or structure created through the interconnection of elongated elements, preferably substantially rigid, in a predefined geometric and topological scheme or pattern.

Preferably, each elementary body 3, with respect to a Cartesian system of axes Xc, Yc, Zc as above defined, wherein the elementary body 3 lies on such a Cartesian system with at least a first elongated lateral element lying on the axis X, an elongated lateral element which lies on axis Y (like the embodiment illustrated in figure 1) is rotated around at least one rotation axis X'', Y'', Z'' parallel to the aforementioned axes Xc, Yc, Zc and passing through a center of gravity of said elementary body 3 of a respective rotation Rx, Ry, Rz (illustrated in the attached figure 2).

In particular, each rotation Rx, Ry, Rz around the respective X'', Y'', Z'' axis is between 0° and 270°.

Preferably, the rotation Rx, Ry, Rz of each elementary body 3 is such that each elementary body 3 adjacent to it is mirrored and/or symmetrical with respect to an axis of symmetry X', Y', Z'.

Advantageously, as described in detail below, each of said elementary bodies 3 includes three first vertices 31 and three second vertices 32. Preferably, each of said elementary bodies 3 includes elongated elements 5, 6, 7 arranged to connect between said first vertices 31 and/or said second vertices 32.

The auxetic metamaterial thus obtained, i.e. made through the interconnection of elongated elements 5, 6, 7, it has a porosity greater than 70% and preferably greater than 80%, wherein "porosity" means the ratio between the empty volume (i.e. the internal volume that remains defined between the elongated elements) and the global volume of the metamaterial.

These porosity values therefore make it possible to obtain a metamaterial with a low specific weight, resulting in fact a light metamaterial and therefore suitable for any application.

Preferably, in accordance with the preferential but non-limiting embodiment illustrated in the attached figures, each elementary body 3 includes at least a first base of triangular shape defined by three first elongated elements 5 mechanically connected to each other in a triangle at three first vertices 31.

Preferably, each elementary body 3 also includes at least a second base of triangular shape, arranged facing said first base, defined by three second elongated elements 6 mechanically connected to each other in a triangle at three second vertices 32.

The elementary body 3 of the auxetic metamaterial according to the present invention has a prismatic shape with a triangular base in order to increase the rigidity of the elementary body itself and, at the same time, reduce the construction complexity of the metamaterial in question.

Advantageously, the first and second elongated elements 5, 6 have a prismatic, preferably cylindrical, shape. Obviously, the elongated elements 5, 6 may have any elongated shape known to those skilled in the art without thereby departing from the scope of protection of this patent.

Conveniently, each elementary body 3 comprises lateral elongated elements 7 arranged to connect said first vertices 31 with said second vertices 32.

Preferably, the lateral elongated elements 7 develop transversely with respect to the first elongated elements 5 and, preferably, also transversely with respect to the second elongated elements 6.

Similarly, the lateral elongated elements 7 have a prismatic, preferably cylindrical, shape. Obviously, the lateral elongated elements 7 may have any elongated shape known to those skilled in the art without thereby departing from the scope of protection of this patent.

Preferably, each of the first three elongated elements 5 has a prevalent extension equal to the other first elongated elements 5. In other words, preferably the first three elongated elements 5 define an equilateral triangle base. In other words, each first elongated element 5 of each elementary body 3 defines, with a first contiguous elongated element (connected to it by a corresponding first vertex 31) an angle of approximately 60°.

Similarly, preferably, each of the second three elongated elements 6 is provided with a prevalent extension equal to the other second elongated elements 6. In other words, preferably the second three elongated elements 6 define an equilateral triangle base. In other words, each second elongated element 6 of each elementary body 3 defines, with a second contiguous elongated element (connected to it by a corresponding second vertex 32) an angle of approximately 60°.

Advantageously, said elastically yielding connection means 4 comprise connection beams 8, placed to connect first vertices 31 and/or second vertices 32 of a said elementary body 3 with first vertices 31 and/or second vertices 32 of at least one said elementary body 3 contiguous.

Obviously, the connection means 4 may be of any type, even different from the particular connection beams 8, without thereby departing from the scope of protection of this patent. For example, the connection means 4 may provide a punctual connection between vertices of the elementary bodies 3 or may include two or more connection beams 8 parallel to each other.

The connection beams 8 of the connection means 4 are configured to deform elastically and to allow rotation of the connected elementary bodies 3.

Operationally, following the application of a stress on the operating cell 2, the elementary bodies 3 rotate through the elastic deformation of the connection means 4. For example, following an axial compression (for example vertical) of the operating cell 2, the elementary bodies 3 rotate around the connection beams 8 (in the case of figure 5 in an anti-clockwise direction), decreasing the transversal bulk (horizontal in the exemplary case) of the operating cell 2. Otherwise, following a stretching (for example vertical) the elementary bodies 3 rotate around the junction beams 8 (in the case of figure 5 clockwise), increasing the transversal size (horizontal in the exemplary case) of the operating cell 2.

The movement (in particular the rotation) of the elementary bodies 3 through the deformation of the connection means 4 is due to the geometry, and in particular to the shape of the individual elementary bodies 3, as well as to the connection of the elementary bodies 3 at their vertices 31, 32.

In other words, by applying a stress on said operating cells 2, for example compression, through an action parallel to the axis Y, a rotation of the elementary bodies 3 is caused, with a consequent elastic bending of the connection beams 8 between the adjacent elementary bodies. Consequently, the angle defined between two contiguous elementary bodies 3, and in particular between two elongated elements 5, 6 of two contiguous elementary bodies 3, decreases, thus manifesting auxetic behavior, therefore, a negative Poisson coefficient.

The spatial and three-dimensional composition of the elementary bodies 3 allows the construction of spongy (or porous) structures of any size, in particular formed by chiral and auxetic operating cells 2 as illustrated in the attached figures.

Advantageously, the auxetic metamaterial used in the supporting structure 500 - and in the lateral wall 400 - of the vertebral prosthesis 1 according to the invention, in use, is configured to generate micromovements that simulate the movement of the vertebrae.

The metamaterial of the supporting structure 500 thus created allows obtaining a stiffness very similar to that of human trabecular bones, thanks to the auxetic behavior and its chiral geometry which makes up the elementary bodies 3.

For the purposes of this patent, the term "chiral" shall be understood as a structure of rigid elements connected to each other by means of flexible connections. In other words, the term "chiral" shall be understood as meaning a structure (reticular or cellular or trabecular) made with rotating units connected to each other by means of connections.

In particular, said operating cell 2 has auxetic behavior with an apparent elasticity modulus between 0.1 GPa and 1 GPa.

Advantageously, each elementary body 3 includes elongated reinforcing elements 71 arranged transversally to connect said first vertices 31 with corresponding said second vertices 32, placed inclined between said elongated lateral elements 7.

Conveniently, the elongated reinforcing elements 71 are configured to provide each elementary body 3 with greater rigidity and mechanical stability, in particular during their movement.

According to an embodiment not illustrated in the attached figures, the connection means 4 can only provide a substantially punctual connection between vertices 31, 32 of adjacent elementary bodies 3. In other words, the connection beams 8 of the connection means 4 can have substantially zero length.

In this situation, the torsional stresses of the rotation of the elementary bodies 3 are mostly discharged on the elongated elements 5, 6, 7 of the elementary bodies 3 themselves. Therefore, in this embodiment it is preferable to provide the aforementioned elongated reinforcing elements 71 to give greater rigidity to the elementary bodies 3.

Advantageously, the supporting structure 500 allows to reduce bone degeneration when used as a bone prosthesis, as it emulates the mechanical behavior of the bones adjacent to the prosthesis itself.

Advantageously, said elementary bodies 3 are configured to rotate on said elastically yielding connection means 4 following the exertion of an external force.

With reference to the containment structure 200 and in particular to the lateral wall 400 of the vertebral prosthesis 1 according to the invention, it is also made with an auxetic metamaterial, for example illustrated in the attached figures 4-6.

With particular reference to the attached figure 5b, the auxetic metamaterial of the lateral wall 200 comprises a plurality of elementary cells 50. Said elementary cell 50 preferably develops planarly and has a thickness smaller than its planar extension, for example it has a thickness between 1÷ 5 mm.

Preferably, the elementary cell 50 is composed of an original geometry that includes four auxetic elements 51 (see figure 5c) of optimized shape and dimensions, and has a substantially constant thickness. Preferably, the thickness of the lateral wall 400 is between 1 and 2 mm.

With reference to FIG. 5c, said auxetic elements 51 of the elementary cell 50 (also known as elementary units) comprise a central body 52, for example substantially square in shape, and a plurality, in particular four, ligaments 53a, 53b, 53c, 53d suitable for connecting each of said auxetic elements 51 with contiguous auxetic elements 51, in particular with four corresponding contiguous auxetic elements 51. In this way, an auxetic structure, of a hybrid type, i.e. anti-tetrachiral with rotating elements, is preferably formed.

The aforementioned ligaments 53a, 53b, 53c, 53d have recesses, which define an angle of width α with the central body 52. In particular, the recesses defined between the ligaments 53a, 53b, 53c, 53d and the central body 52 are created through the combination of variable arc parametric spline curves. According to a preferred embodiment, said angle α is between 5° and 90°, preferably between 5° and 60°.

The union of a plurality of elementary cells 50 allows to obtain auxetic structures defining the lateral wall 400 illustrated in the attached figures.

Figure 6 shows a top plan view of a section of a lateral wall 400 wherein the elementary cells 50 are arranged along specific circular sectors of variable length and known radius. In this way, a structure with a profile similar to those of human vertebral bodies is advantageously created, capable of obtaining macro-mechanical properties similar to those of cortical bone.

The cross section illustrated in figure 6 is obtained from the composition of four circular sectors 300a, 300b, 300c, 300d tangent to each other, each preferably having a specific angular width. More in detail, the circular sectors are defined respectively as a central sector 300a, of radius rc; two peduncular sectors 300b, 300c, of radius rp and a spinal sector 300d, of radius rs.

Preferably, the dimensions of said circular sectors 300a, 300b, 300c, 300d are comparable to those of the human vertebral cortical bone. Operationally, the morphology described is obtained on the basis of the geometric dimensions of human vertebrae, extrapolated from computerized tomographic images, in such a way as to reproduce the same shape of the vertebral cortical bone, which is defined as body.

The particular geometry of the lateral wall 400 gives the vertebral prosthesis 1 auxetic properties and a reduced apparent elastic modulus, capable of guaranteeing better osteointegration, reducing bone hypostress phenomena.

By stressing said elements into compression, by action along the vertical ligaments of the structure, a rotation of the central bodies 52 of the elementary units 51 of the lateral wall is caused, with a consequent reduction of the angle α. This behavior produces a flexion of the four ligaments 53a, 53b, 53c, 53d thus manifesting auxetic behavior, therefore a negative Poisson's ratio.

This deformation mechanism, combined with the specific morphology of the lateral wall 400 and the supporting structure 200, causes a phenomenon of global auxetics of the vertebral prosthesis 1 itself which, in particular, translates into a reduction of its total bulk. In particular, the compression involves a decrease in the characteristic radius rc, rp, rs of each single portion of the section of the lateral wall 400, with consequent auxetic behavior of the vertebral prosthesis 1, that is, in a transverse contraction with a reduction in the volume occupied by the prosthesis 1.

From what has been described it is clear that the vertebral prosthesis, according to the invention, is particularly advantageous as:

- is able to overcome, at least in part, the drawbacks of the prior art mentioned above;
- emulates the mechanical behavior of natural bones;
- it is structurally resistant and reliable;
- it is functionally completely reliable;
- it can be manufactured on an industrial level with known manufacturing techniques, such as three-dimensional printing in particular;
- ensures correct bone regrowth within it, stimulating bone cell growth within its porous structure;
- increases the fatigue life of the prosthetic implant;
- reduces the stiffness of the entire prosthesis system within which it is implanted;
- avoids contact with adjacent healthy tissues thanks to its auxetic behavior;
- has an alternative and/or improved configuration, both in constructive and functional terms, compared to traditional known solutions.

It is clear from the above description how the vertebral prosthesis which is the subject of the present invention allows the intended objectives to be achieved.

The present invention has been illustrated and described in one of its preferred embodiments, but it is understood that executive variations could be made to it in practice, without however departing from the scope of protection of the present patent for industrial invention.

CLAIMS

1. Vertebral bone prothesis (1), intended to be mechanically connected to a user's spinal column, comprising:

- at least one containment structure (200), comprising at least two bases (300) spaced apart from each other and at least one lateral wall (400) mechanically connected to said at least two bases (300) at their perimeter edges and made with a metamaterial auxetic preferably a chiral metamaterial;
- at least one supporting structure (500) housed in said containment structure (200) between said two bases (300);

characterized in that said supporting structure (500) is made with an auxetic metamaterial comprising at least one operating cell (2) having a negative Poisson's coefficient.

2. Vertebral prosthesis according to claim 1, characterized in that said operating cell (2) of said supporting structure (500) comprises a plurality of elementary bodies (3) congruent with each other and mechanically connected; each of said elementary bodies (3) has a substantially prismatic shape with a triangular base; said elementary bodies (3) are connected to each other at respective vertices (31, 32) by elastically yielding connection means (4).

3. Vertebral prosthesis according to claim 1 or 2, characterized in that said supporting structure (500) is mechanically connected to said bases (300).

4. Vertebral prosthesis according to one or more of the preceding claims, characterized in that said supporting structure (500) is mechanically released from said lateral wall (400) and defines with said lateral wall (400) an annular chamber (450).

5. Vertebral prosthesis according to one or more of the preceding claims, characterized in that each of said elementary bodies (3) of said supporting structure (500) is a reticular body comprising:

- at least a first triangular-shaped base defined by three first elongated elements (5) mechanically connected to each other in a triangular shape at three first vertices (31);
- at least a second triangular-shaped base, arranged facing said first base, defined by three second elongated elements (6) mechanically connected to each other in a triangular shape at three second vertices (32);
- lateral elongated elements (7) arranged to connect said first vertices (31) with said second vertices (32).

6. Vertebral prosthesis according to one or more of the preceding claims, characterized in that each of said elementary bodies (3) of said supporting structure (500) includes three first vertices and three second vertices; and by the fact that each of said elementary bodies (3) comprises elongated elements (5, 6, 7) connected between said first vertices (31) and/or said second vertices (32).

7. Vertebral prosthesis according to one or more of the preceding claims, characterized in that said elementary bodies (3) are configured to rotate on said elastically yielding connection means (4) following the application of an external force.

8. Vertebral prosthesis according to one or more of the preceding claims, characterized in that said lateral wall (400) is made with an auxetic metamaterial comprising at least one elementary structure (51) having a negative Poisson's coefficient.

9. Vertebral prosthesis according to claim 8, characterized in that said elementary structure (51) develops mainly planar and comprises a central body (51), four ligaments (53a, 53b, 53c, 53d) extending from said central body (52) and able to connect each said elementary structure (51) with contiguous elementary structures (51).

10. Vertebral prosthesis according to one or more of the preceding claims, characterized in that it develops along a main axis X with a substantially constant cross

section and a substantially concave shape.

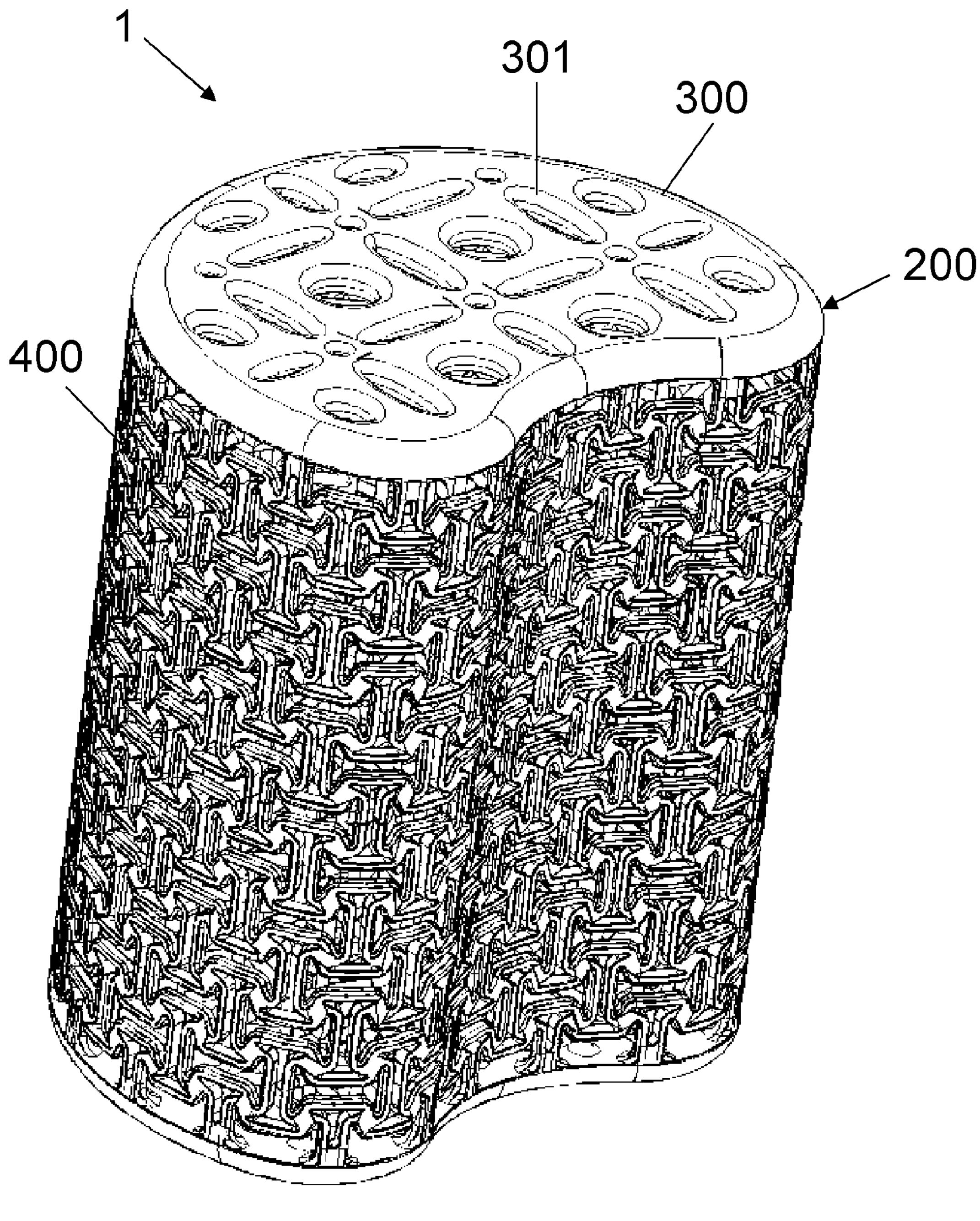

FIG. 1

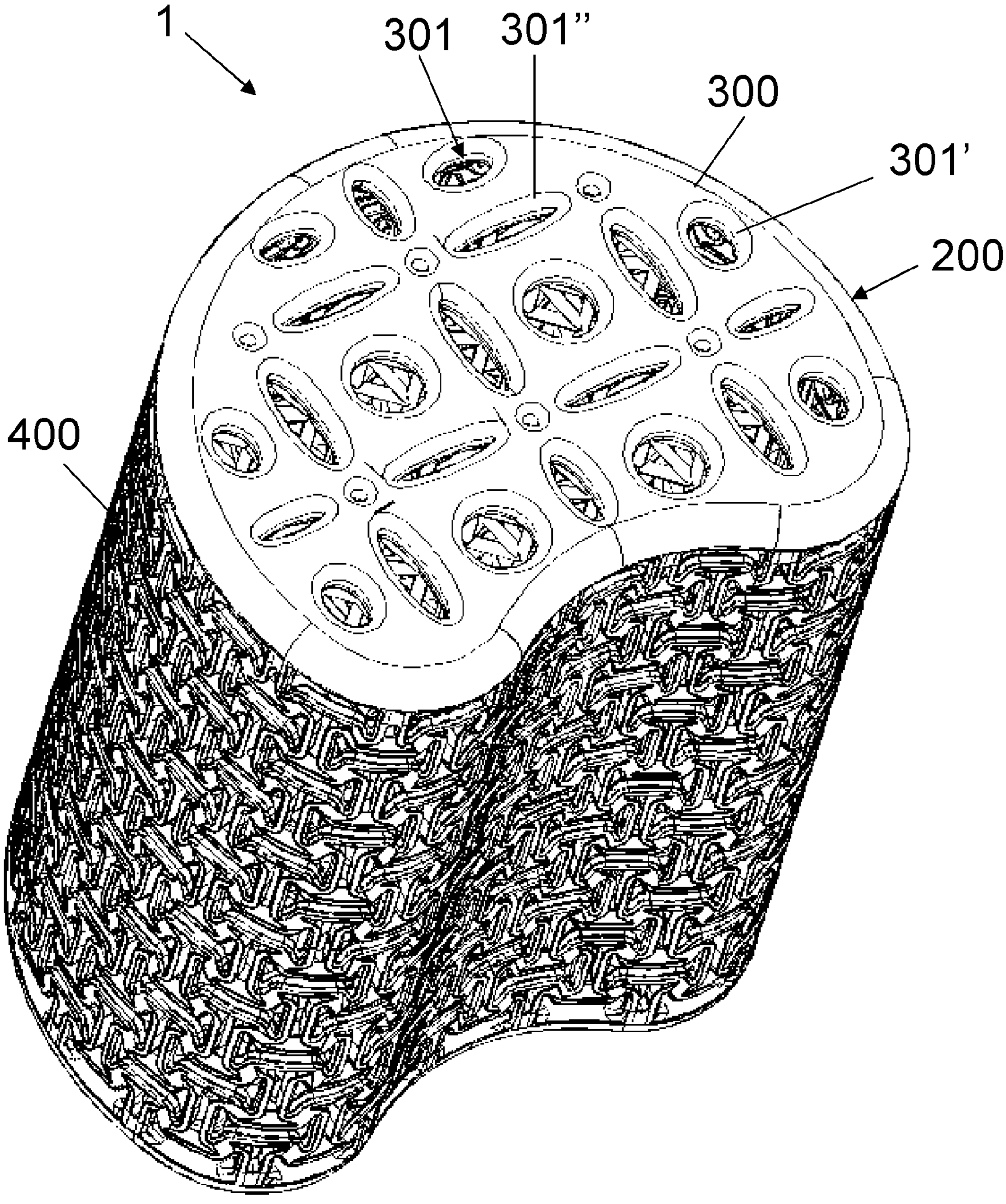

FIG. 2

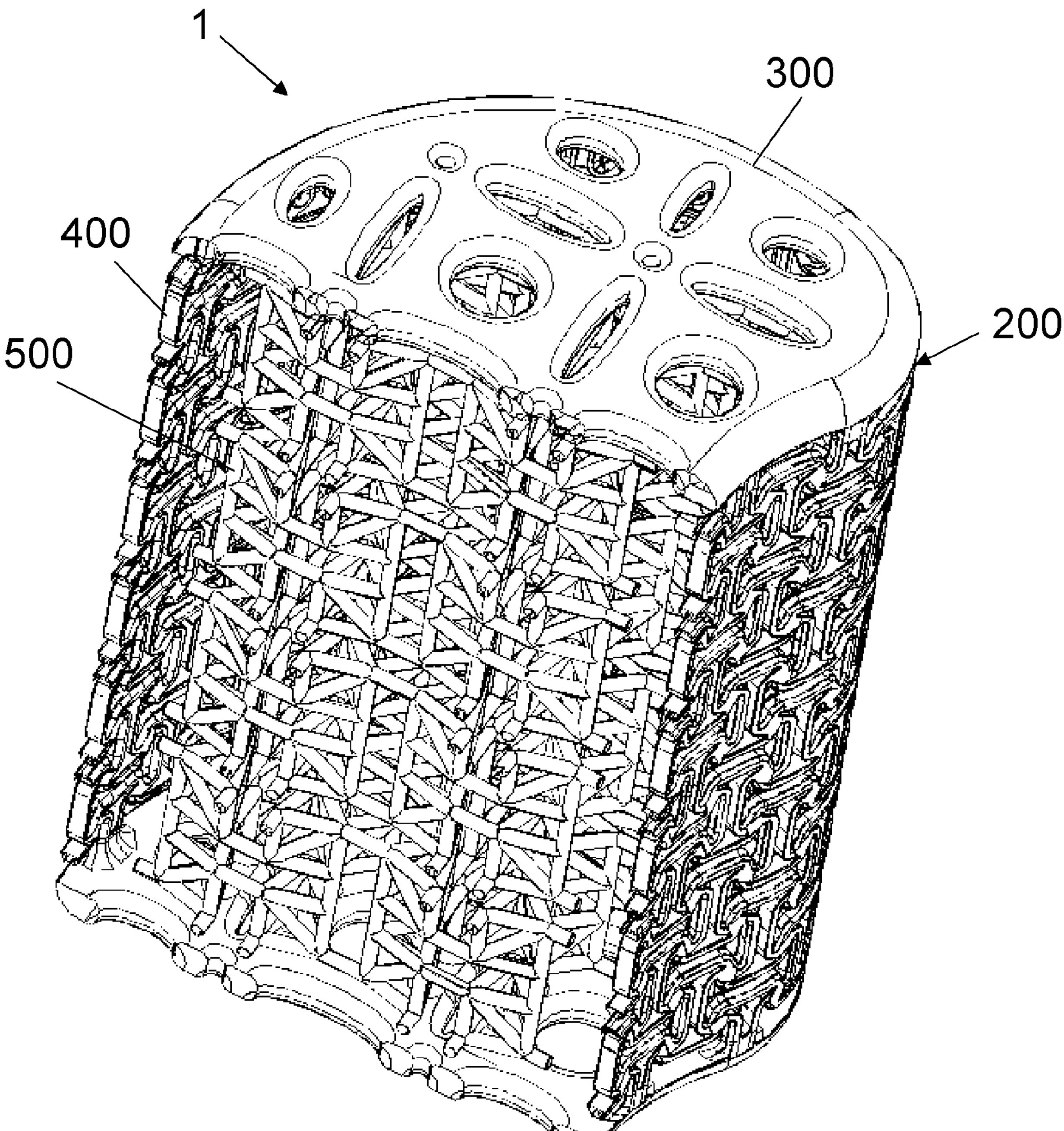

FIG. 3

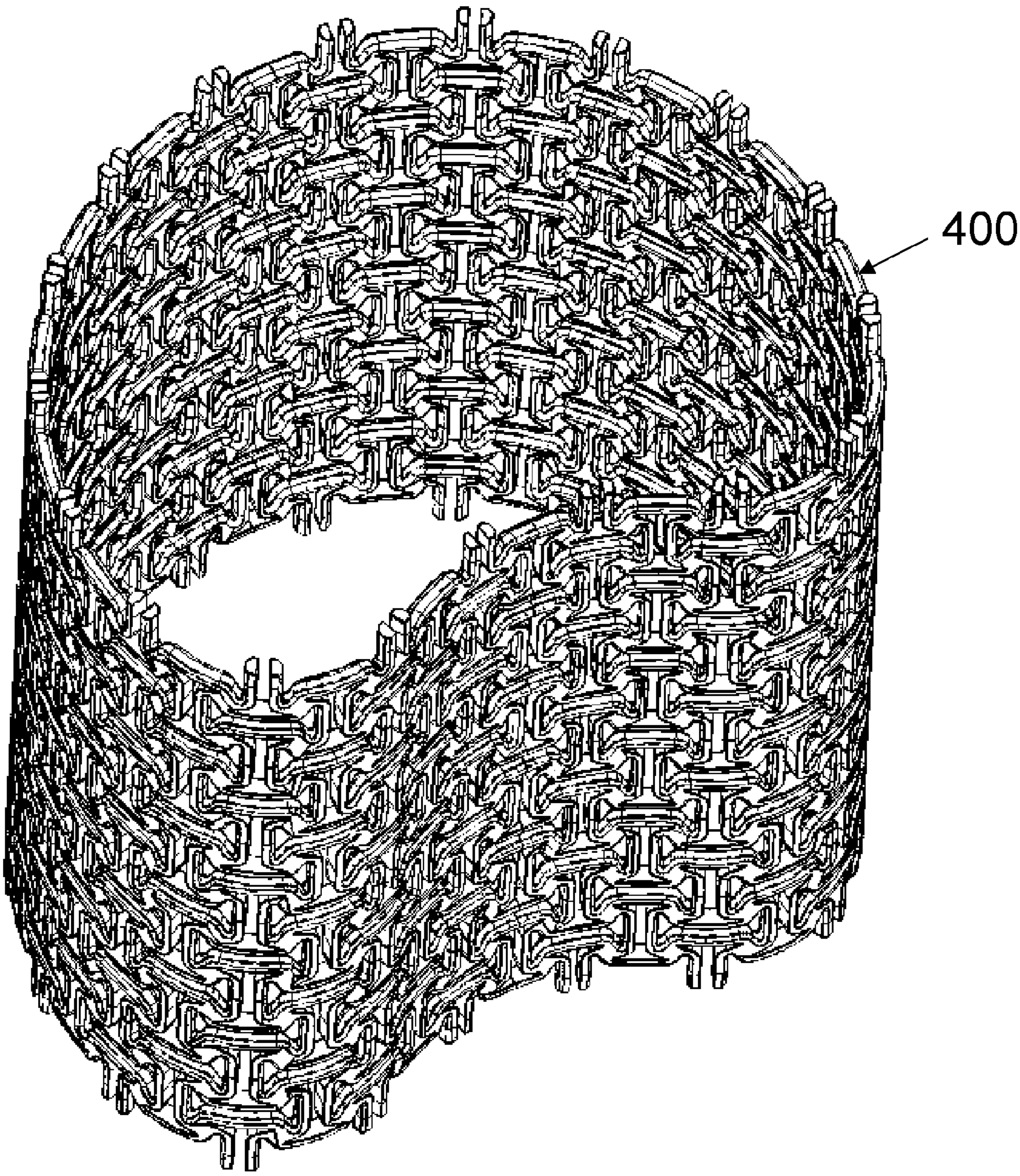

FIG. 4

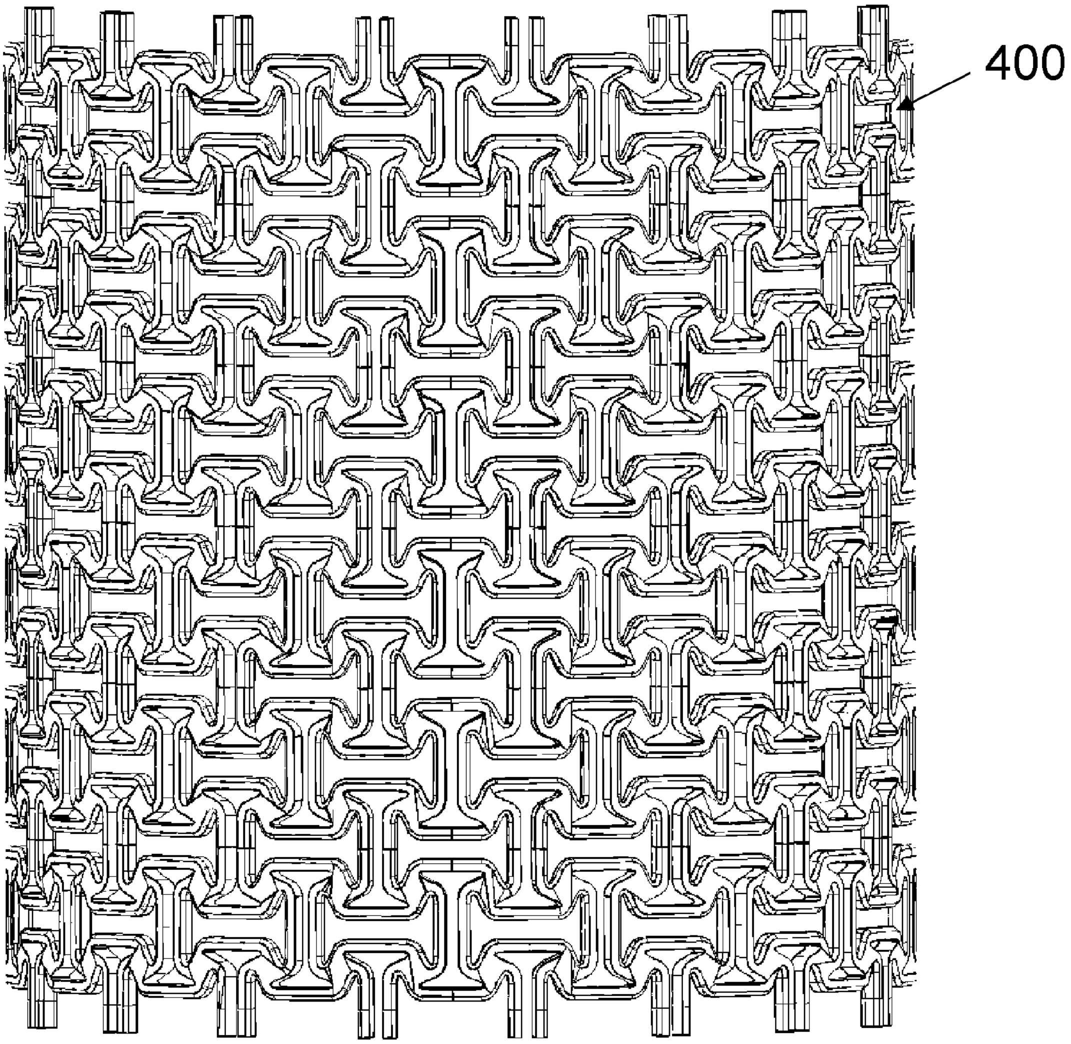

FIG. 5

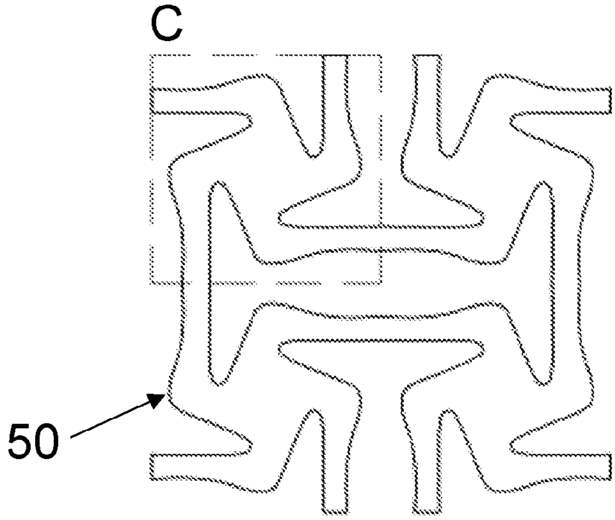

FIG. 5b

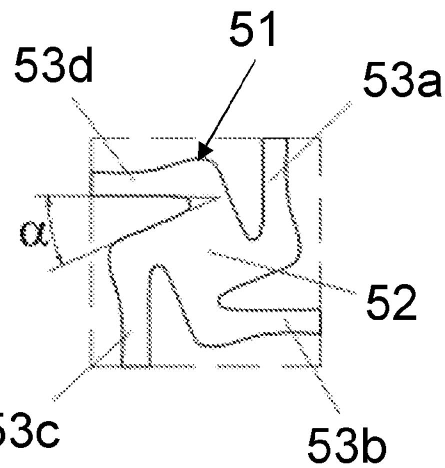

FIG. 5c

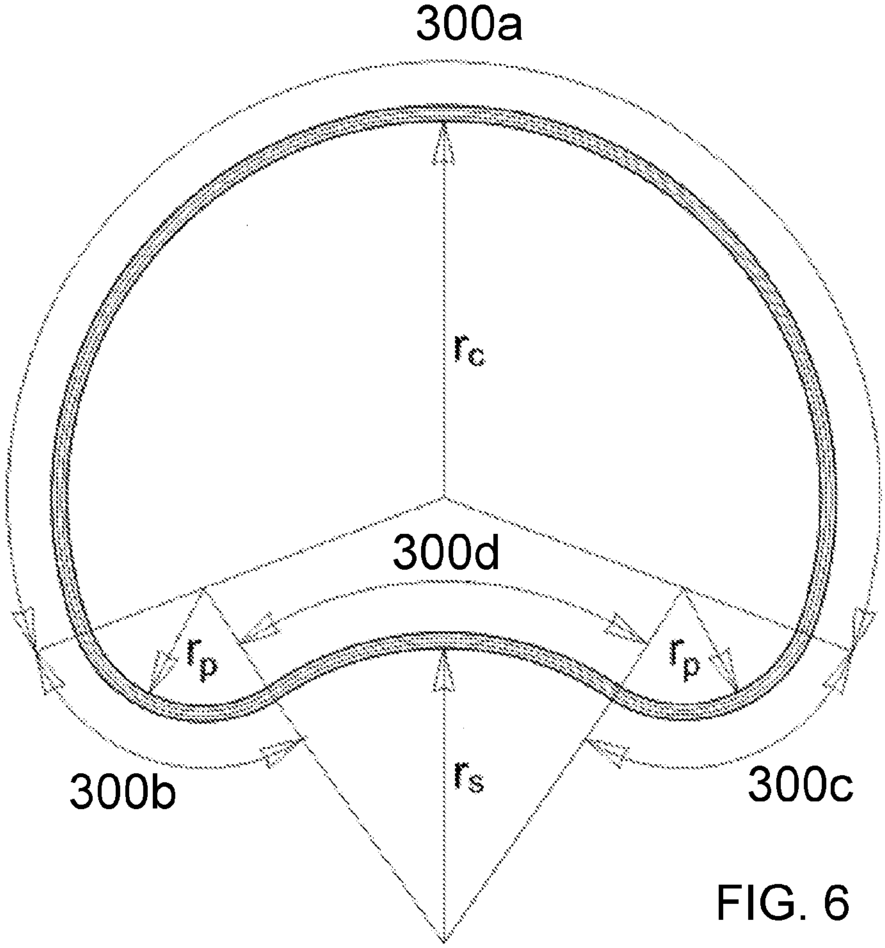

FIG. 6

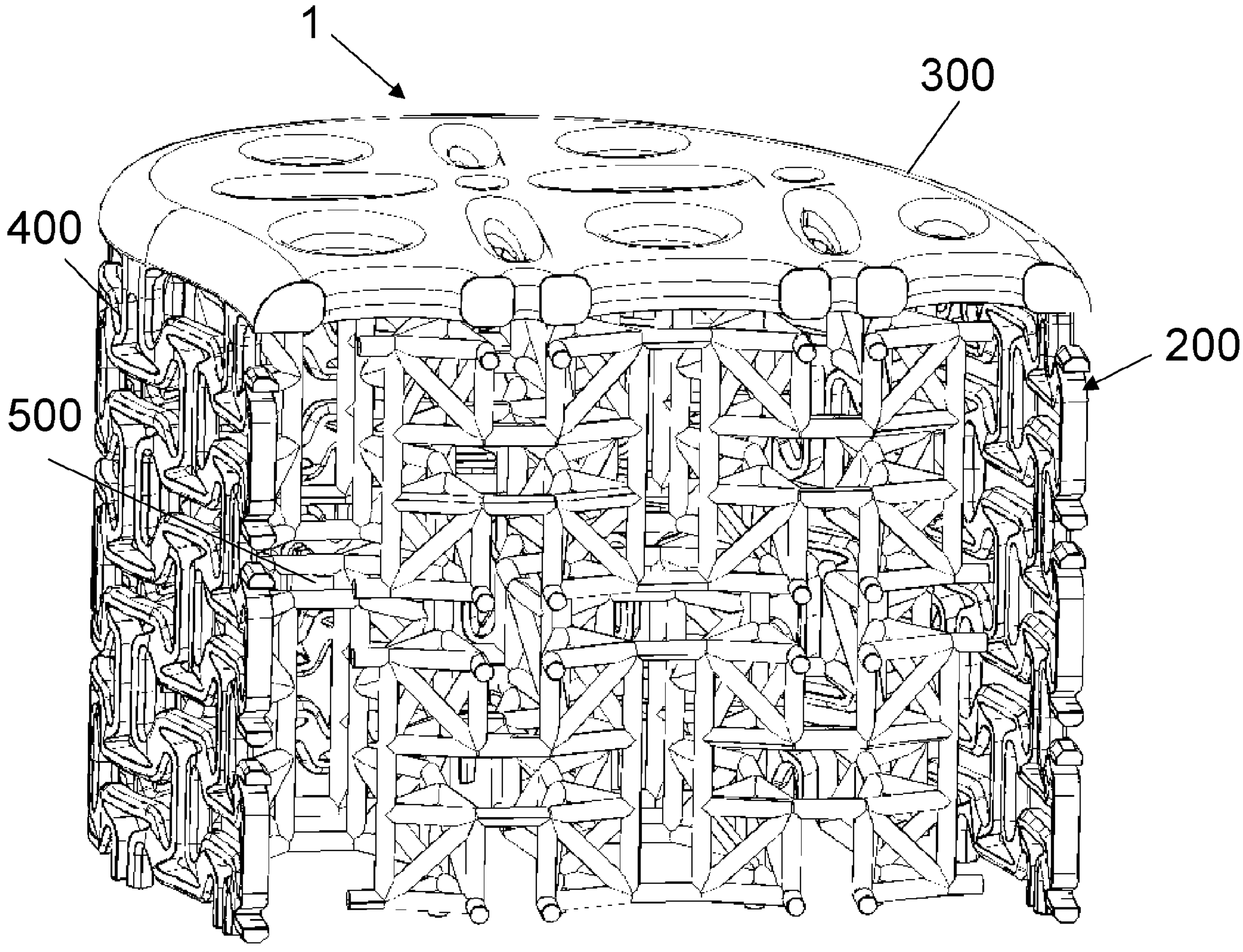

FIG. 7

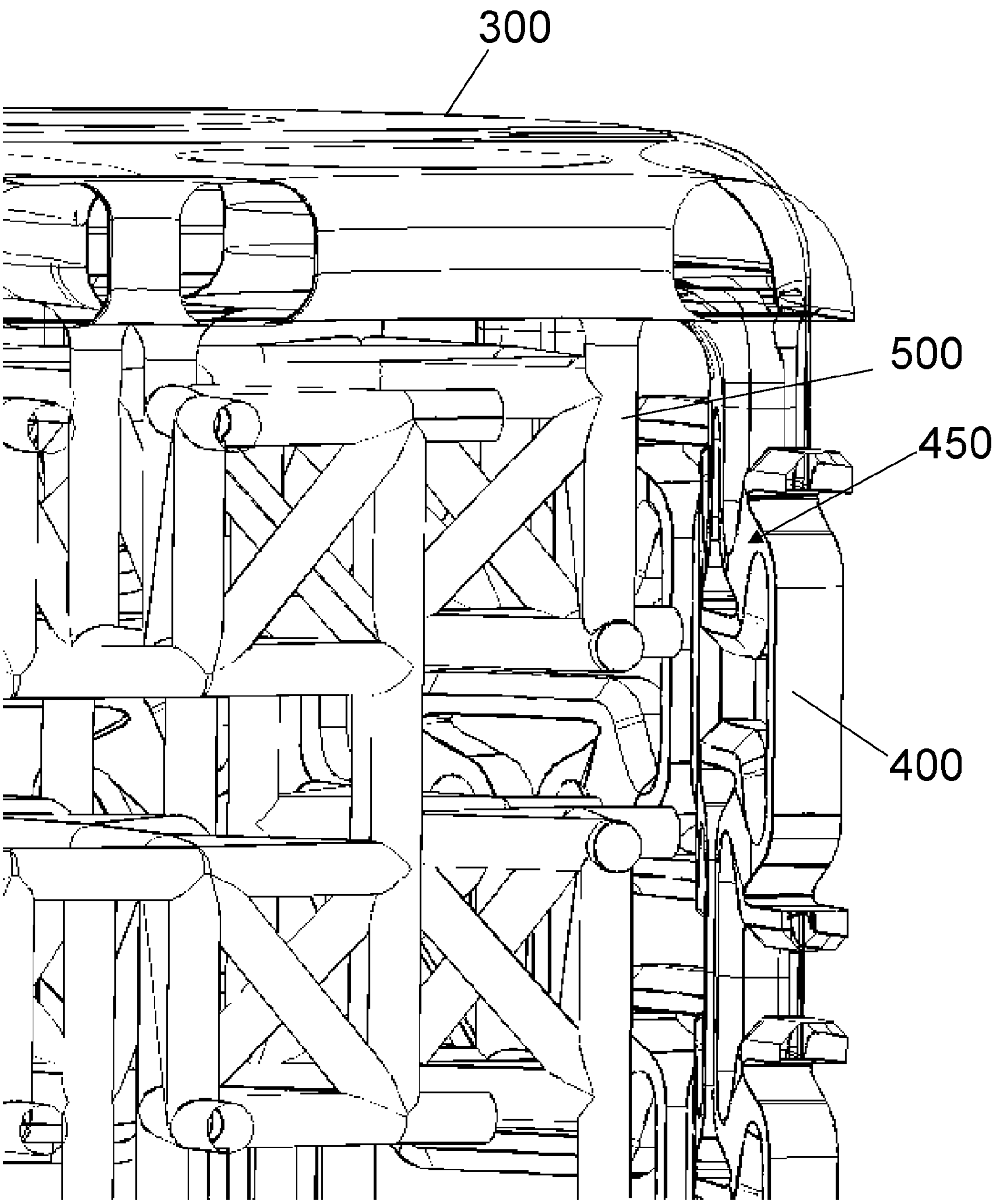

FIG. 8

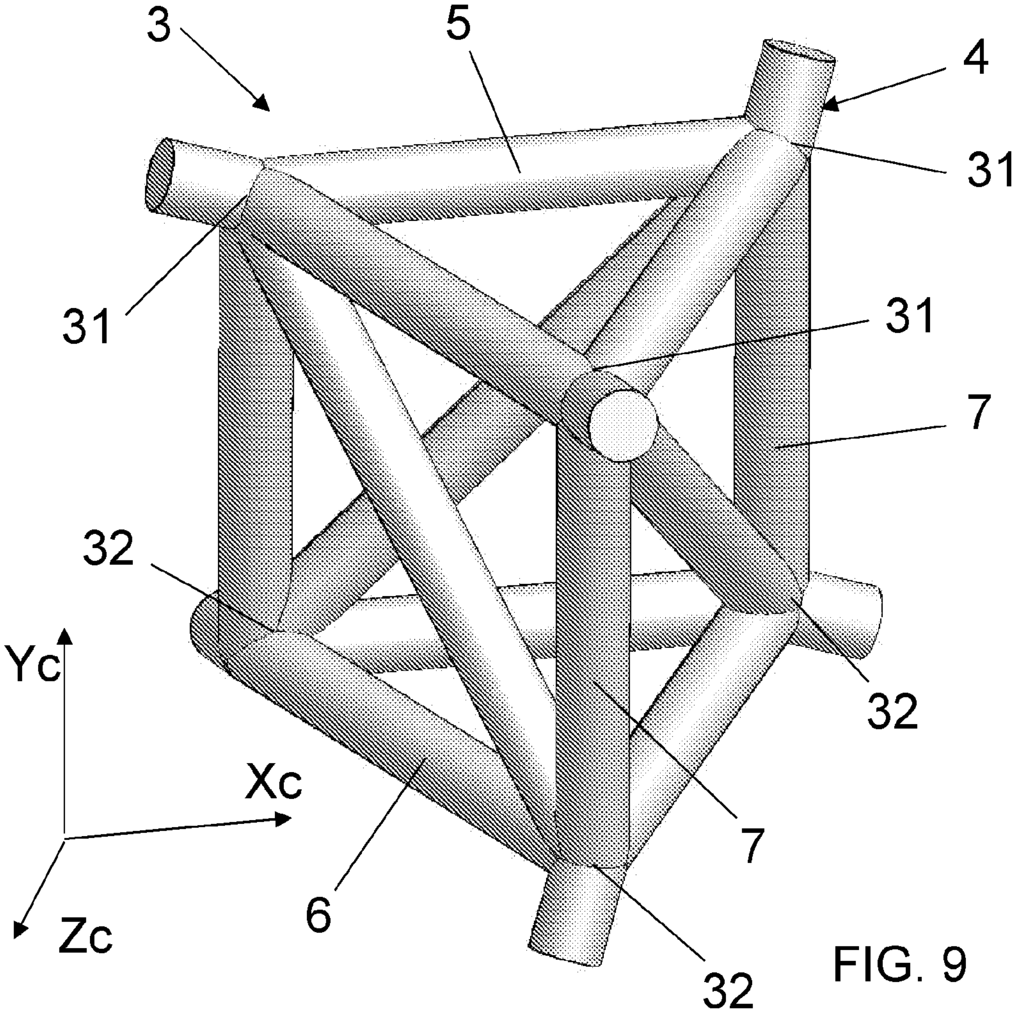

FIG. 9

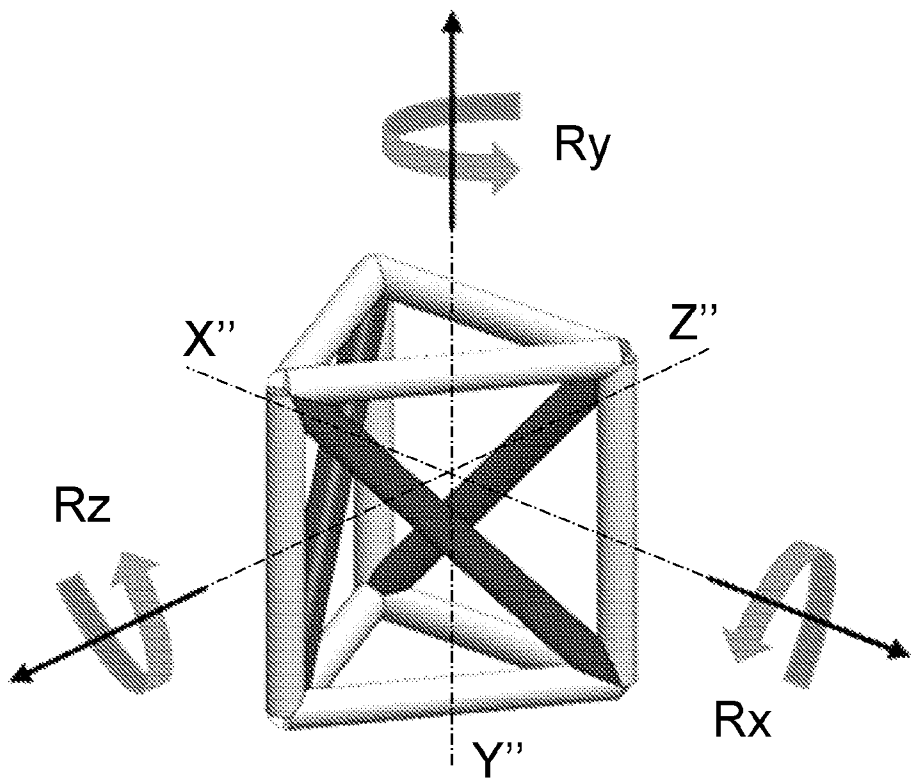

FIG. 10

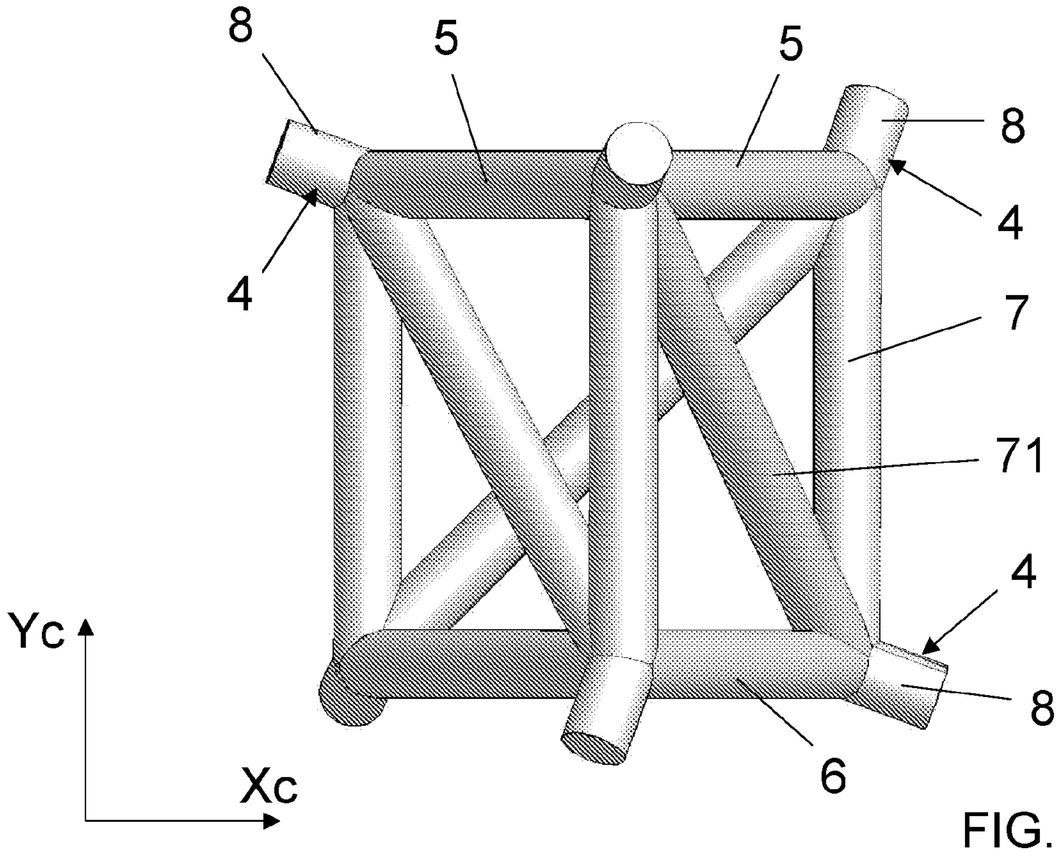

FIG. 11

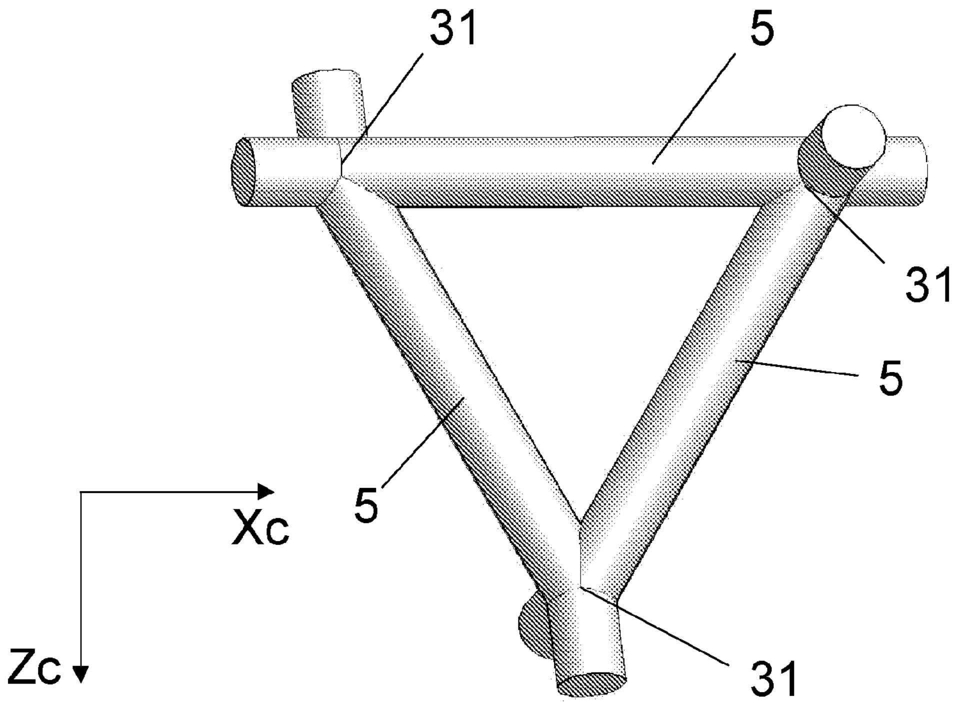

FIG. 12

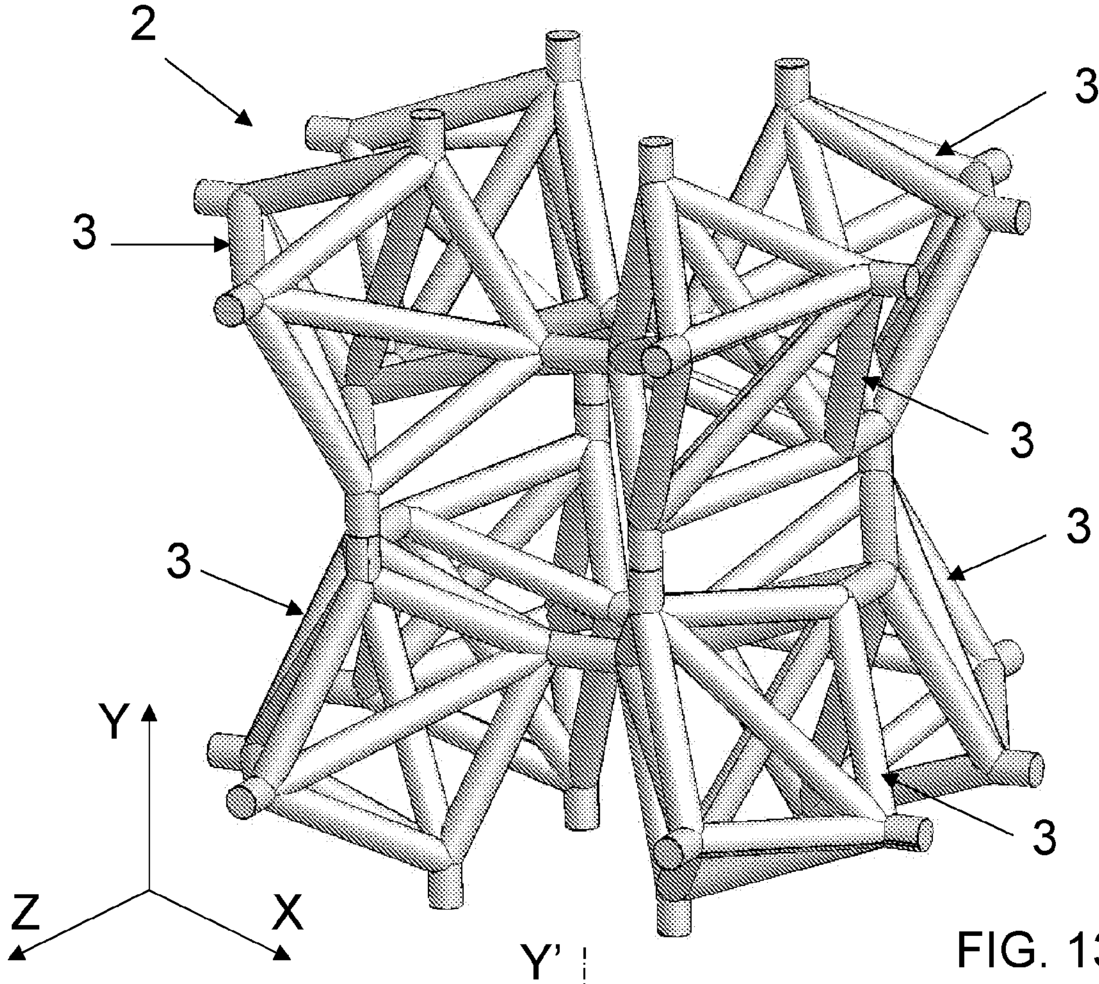

FIG. 13

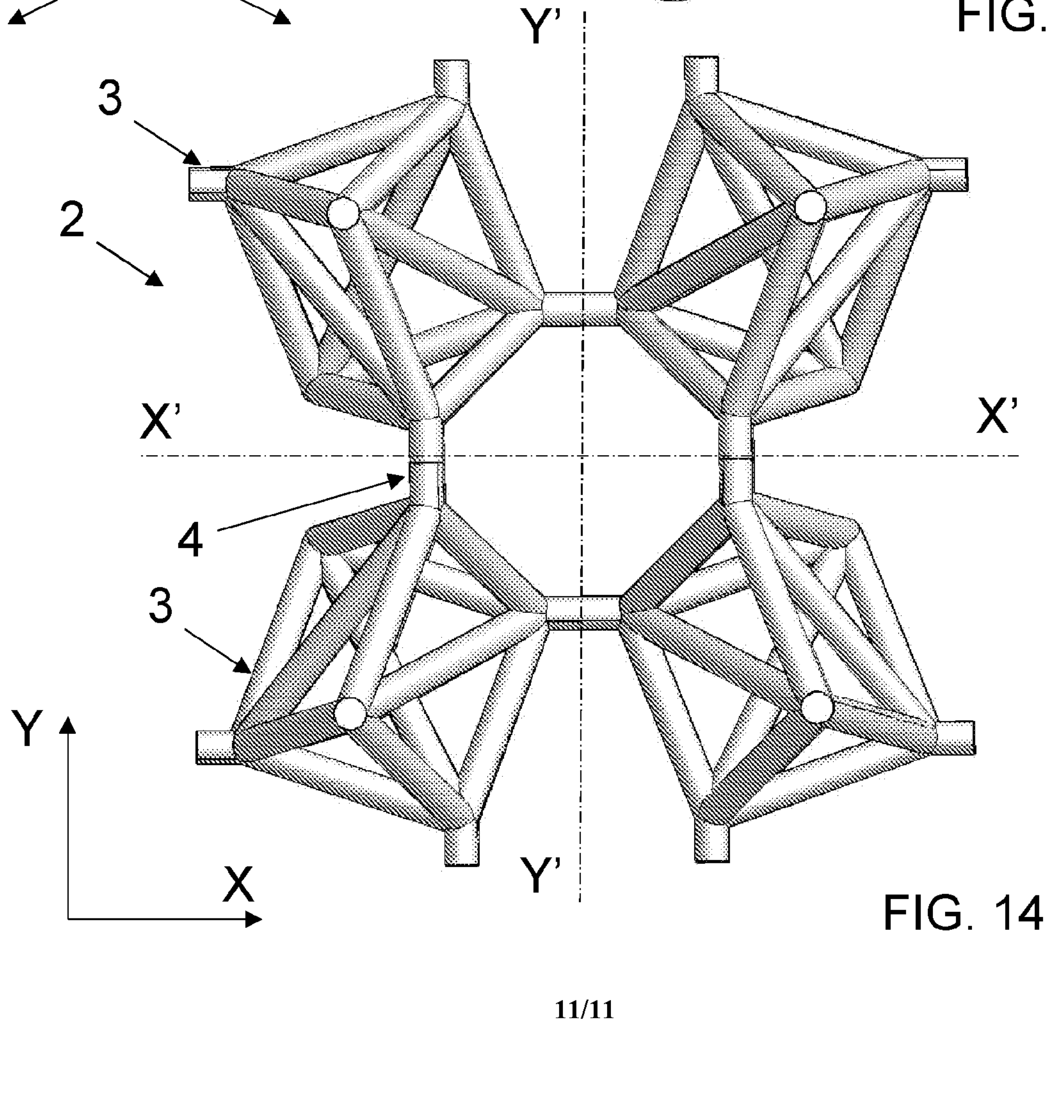

FIG. 14

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2024/051871

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/44 B29C44/34
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F B33Y B29C F16F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2021/245633 A1 (CAERUS MEDICAL [FR]) 9 December 2021 (2021-12-09) claims 1,16-18,22,26-18; figures 1,2A,8A, 13, 14,37A, 38E, 38F,42	1,3,4, 6-10
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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 August 2024	16/08/2024

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Béraud, Florent

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2024/051871

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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A	JIANG YULIN ET AL: "3D-printed auxetic-structured intervertebral disc implant for potential treatment of lumbar herniated disc", BIOACTIVE MATERIALS, vol. 20, 2 June 2022 (2022-06-02), pages 528-538, XP055966320, ISSN: 2452-199X, DOI: 10.1016/j.bioactmat.2022.06.002 page 2; figure 1 page 4; figure 1 -----	1,2,9
A	ZHANG YI ET AL: "A novel buckling-restrained brace with auxetic perforated core: Experimental and numerical studies", ENGINEERING STRUCTURES, vol. 249, 1 December 2021 (2021-12-01), page 113223, XP093084113, AMSTERDAM, NL ISSN: 0141-0296, DOI: 10.1016/j.engstruct.2021.113223 Retrieved from the Internet: URL:https://www.researchgate.net/profile/Yi-Xie-28/publication/355477452_A_novel_buckling-restrained_brace_with_auxetic_perforated_core_Experimental_and_numerical_studies/links/61b9e1f363bbd9324295e877/A-novel-buckling-restrained-brace-with-auxetic-perforated-core-Experimental-and-numerical-studies.pdf> [retrieved on 2023-09-20] page 3 - page 4; figure 1 -----	1,2,7,8
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A	US 2017/362414 A1 (PASINI DAMIANO [CA] ET AL) 21 December 2017 (2017-12-21) figures 1D-1F -----	1,2
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INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2024/051871

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2022/168114 A1 (BERRY BRET MICHAEL [US]) 2 June 2022 (2022-06-02) paragraph [0026] - paragraph [0028]; figures 4-7	1

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Information on patent family members

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