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(51) INT CL:
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US 20080015698 A1
US 20060167552 A1
US 20060122703 A1

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INT CL **A61F**
Other: **EPODOC, WPI**

(54) Title of the Invention: **Modular prosthesis for cervical and lumbar spine**
Abstract Title: **Intervertebral disc prosthesis with modular construction**

(57) The present invention relates to an intervertebral disc prosthesis for the total replacement of an intervertebral disc of the lumbar or cervical spine. The prosthesis has two endplates and middle or intermediate modules 20, 21, 22, where adjacent modules have a recess 32, 33 and corresponding protuberance 30, 31 providing an articulation aurface. Maximal rotation is limited by the shape of the dome or recess, and the flat edges surrounding the dome, which contact each other and limit further rotation. Preferably there are four central plates. Grooves 34 and rails 35 may be provided to prevent translation. Thus articulation around at least two perpendicular axes may be provided.

Fig. 1

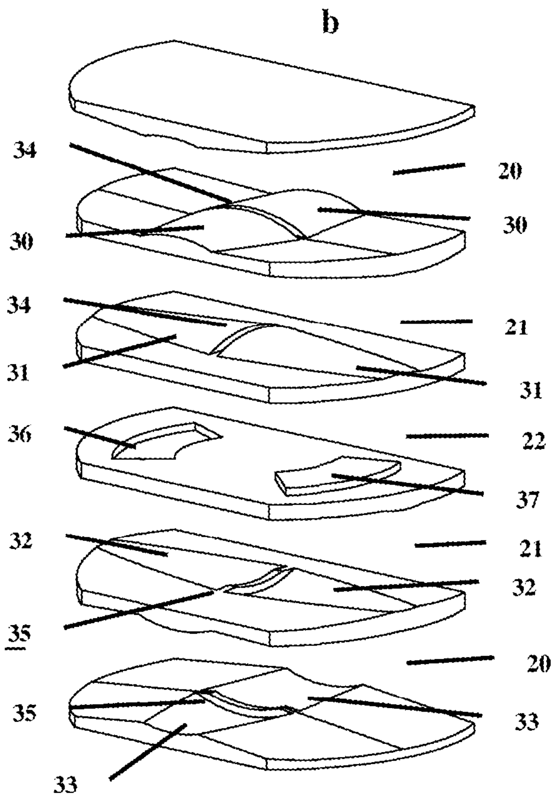

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Fig. 1

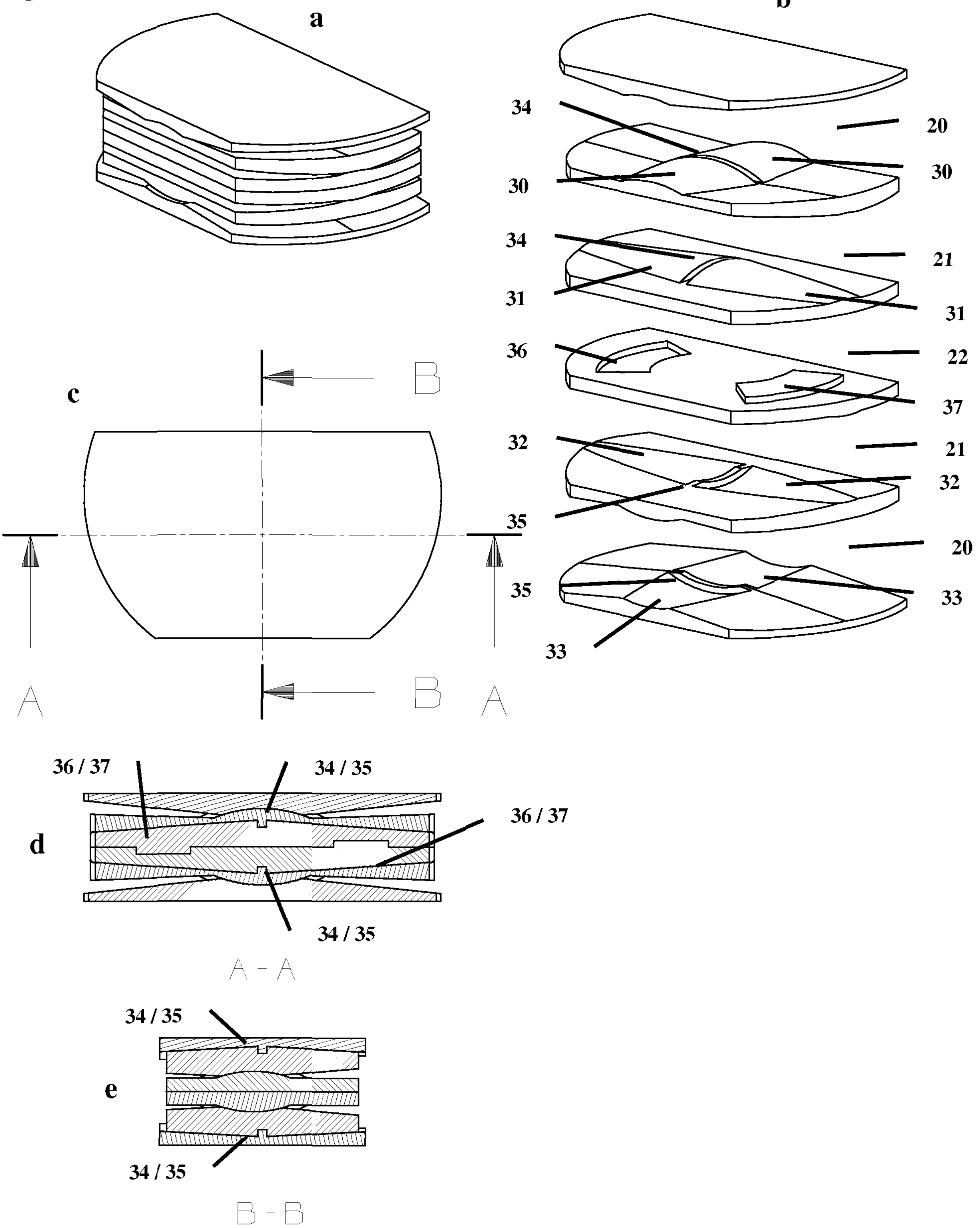
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Fig. 2

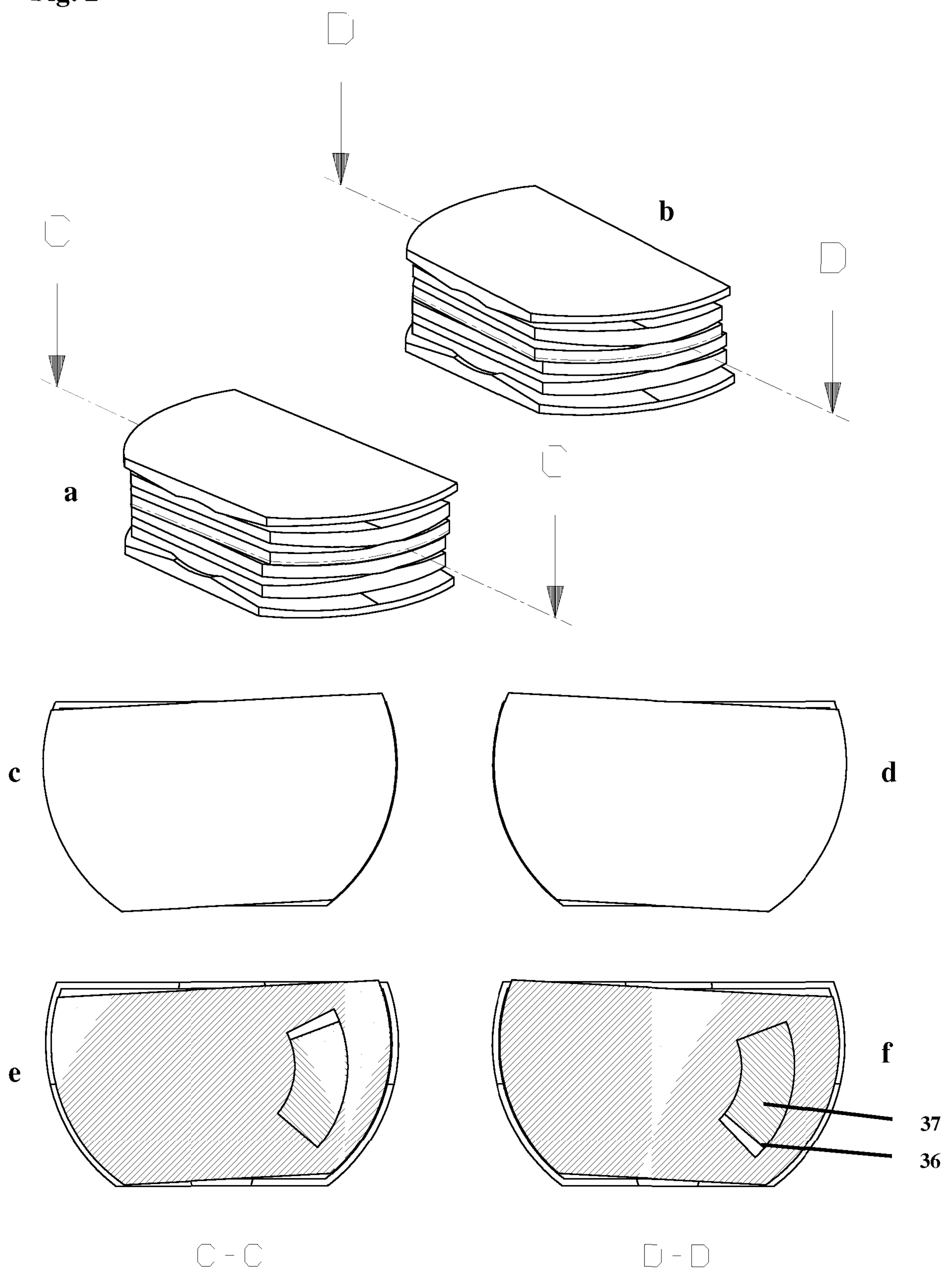


Fig. 3

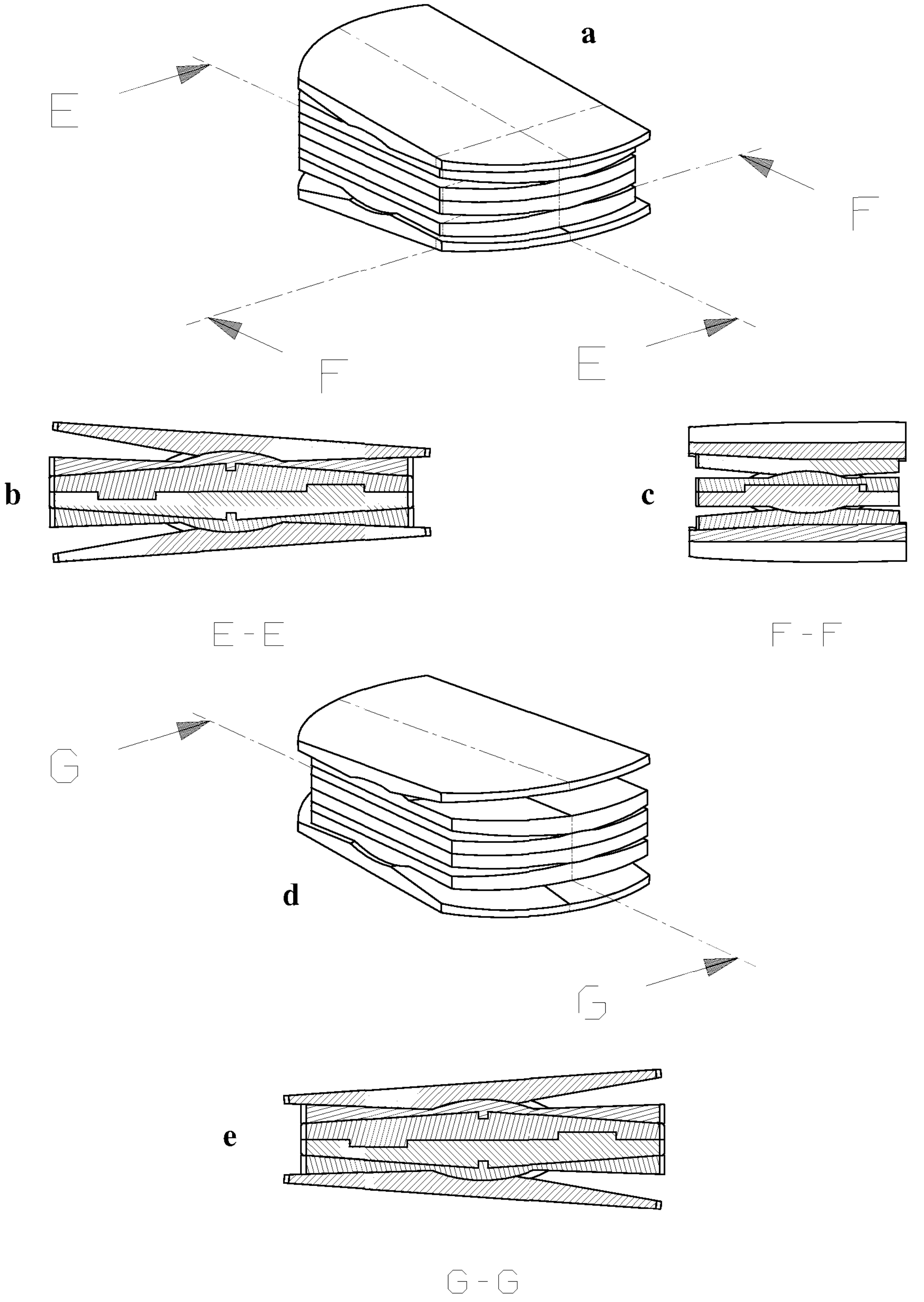


Fig. 4

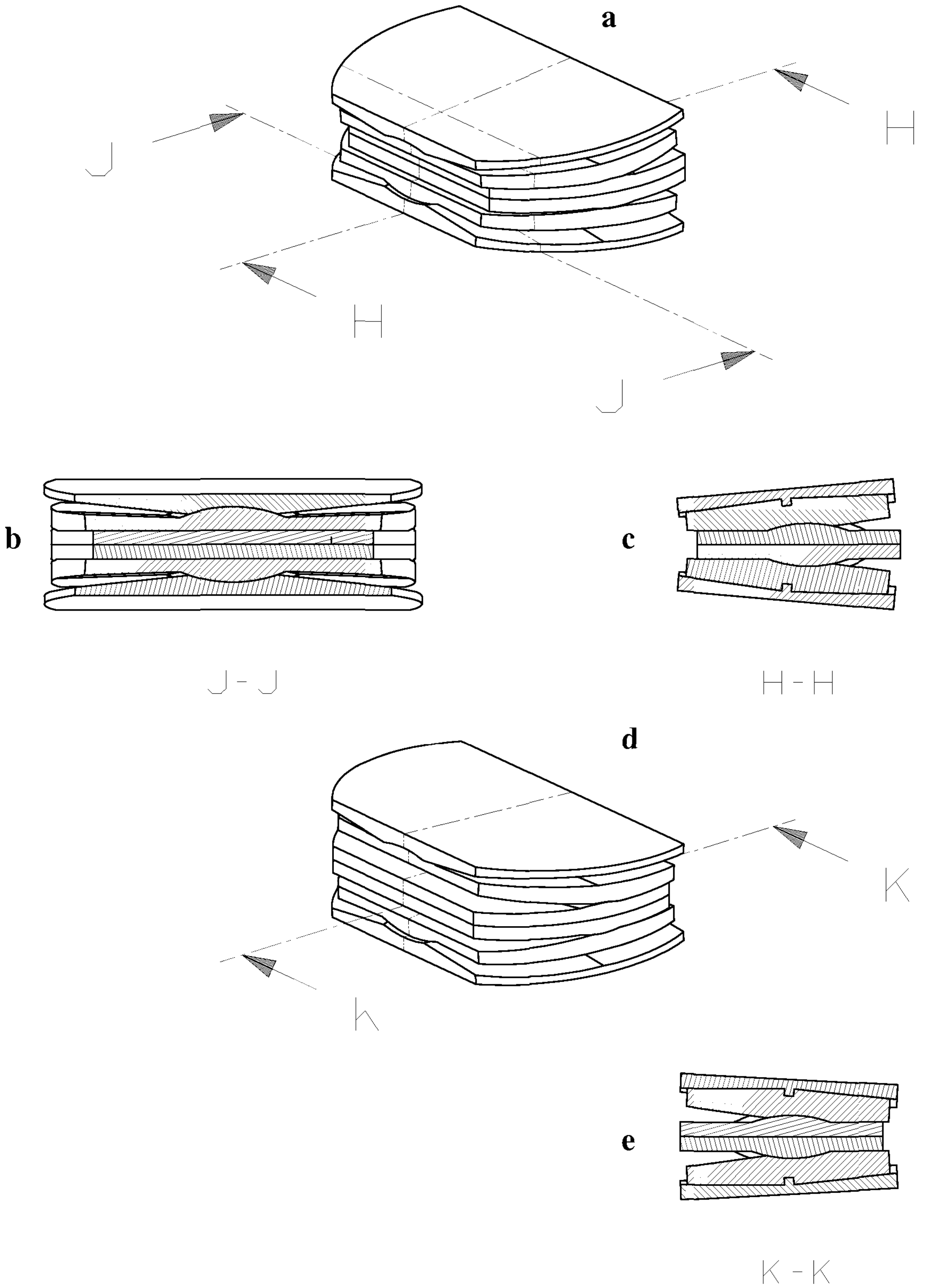


Fig. 5

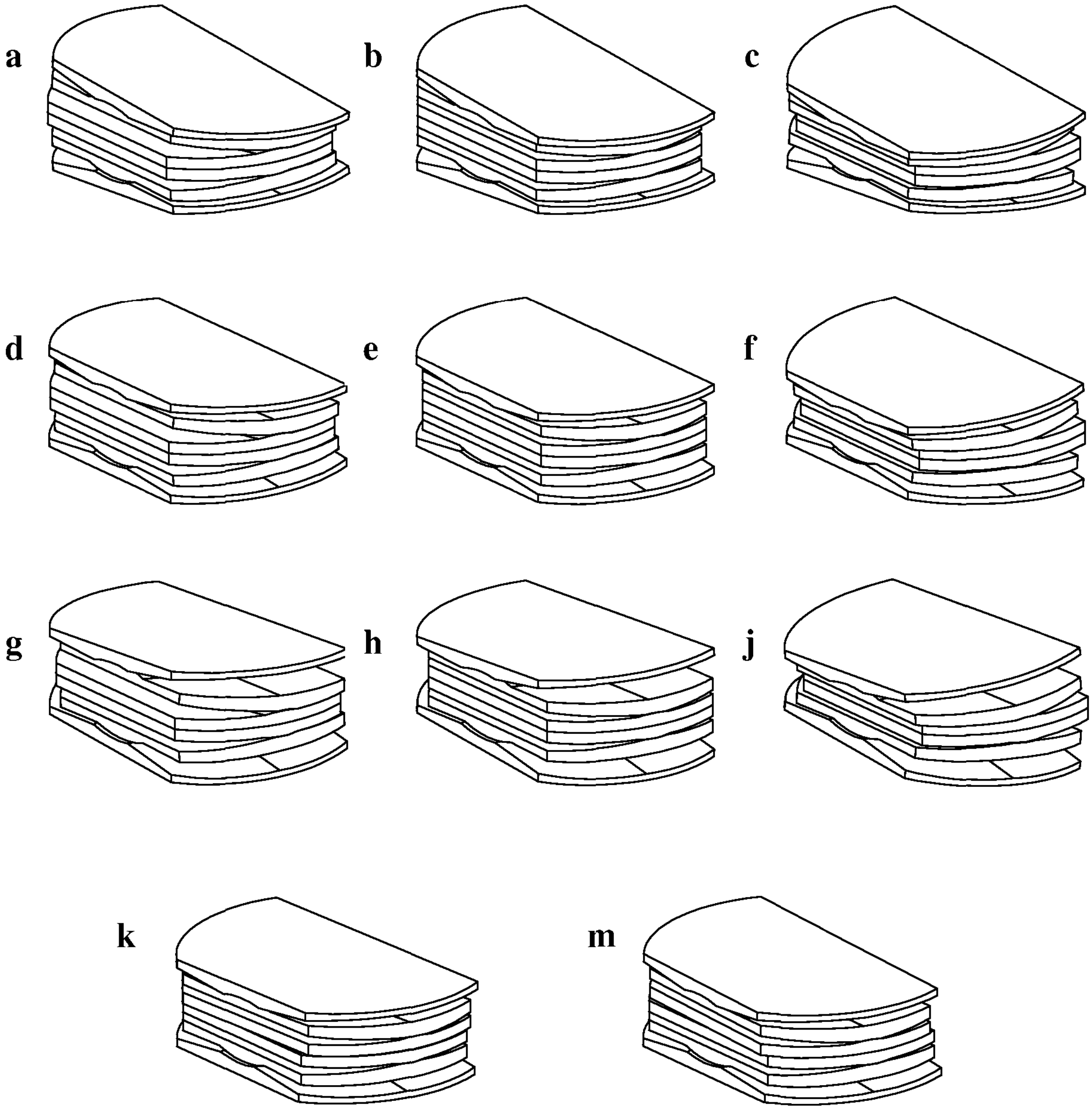


Fig. 6

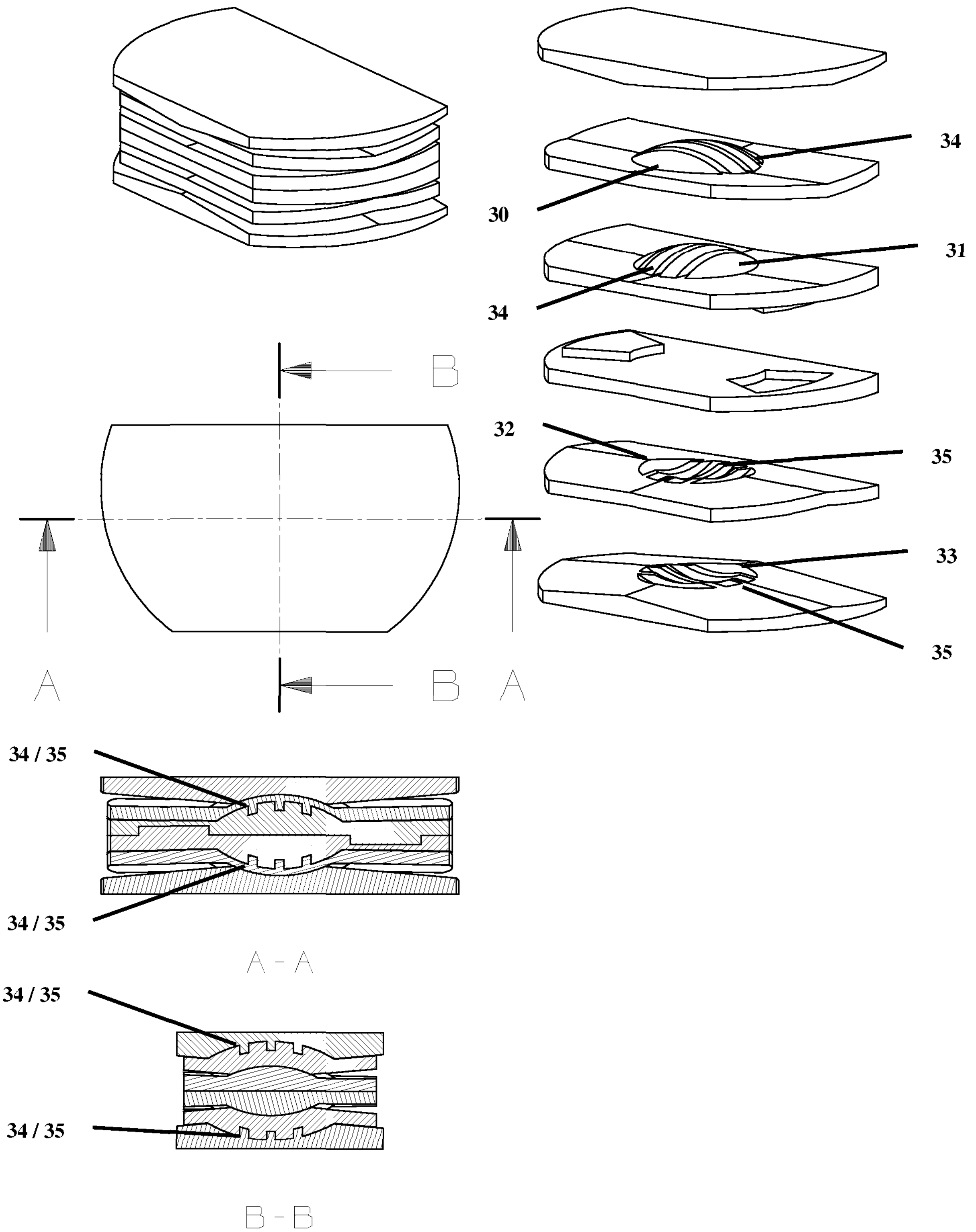


Fig. 7

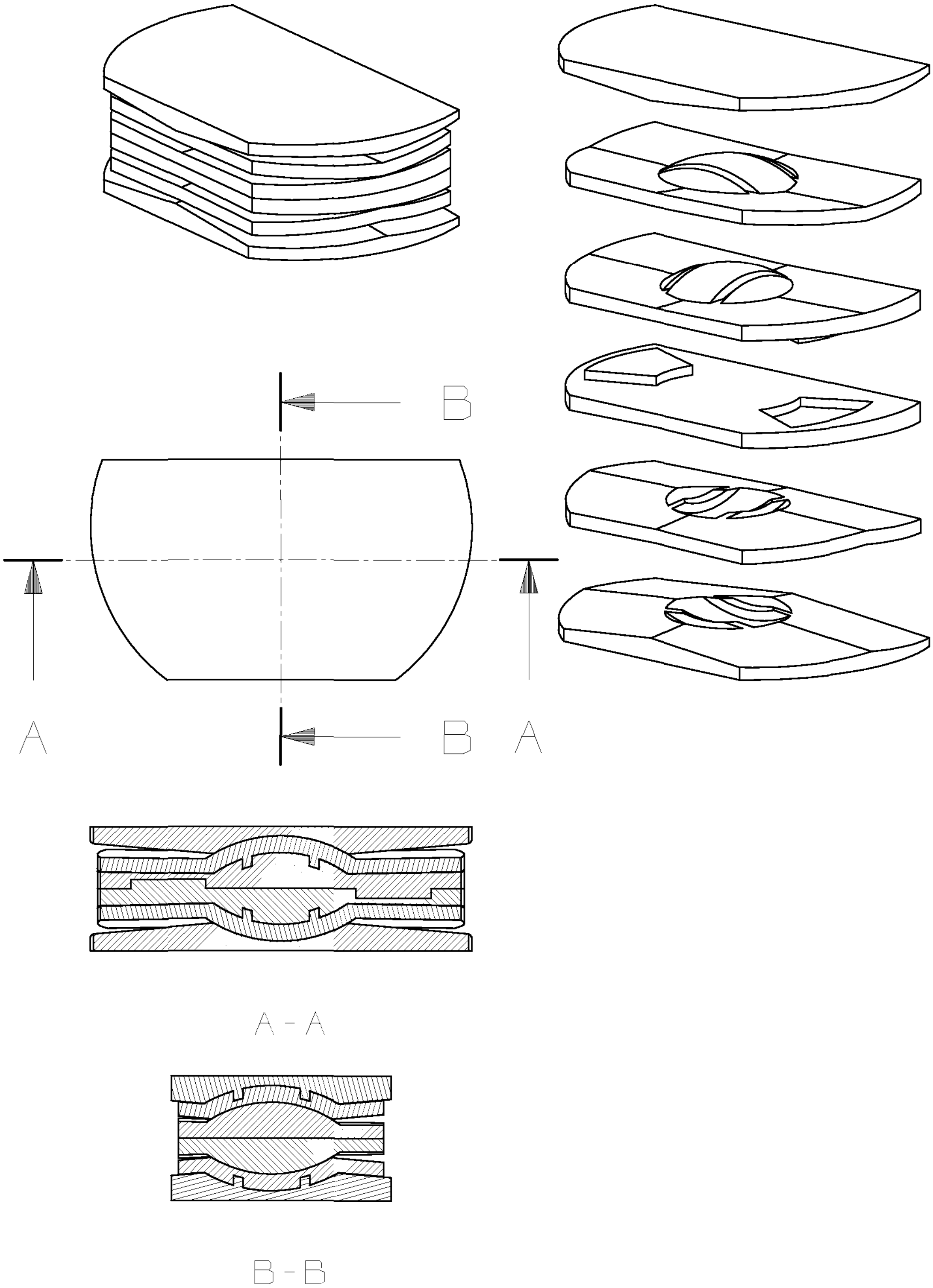


Fig. 8

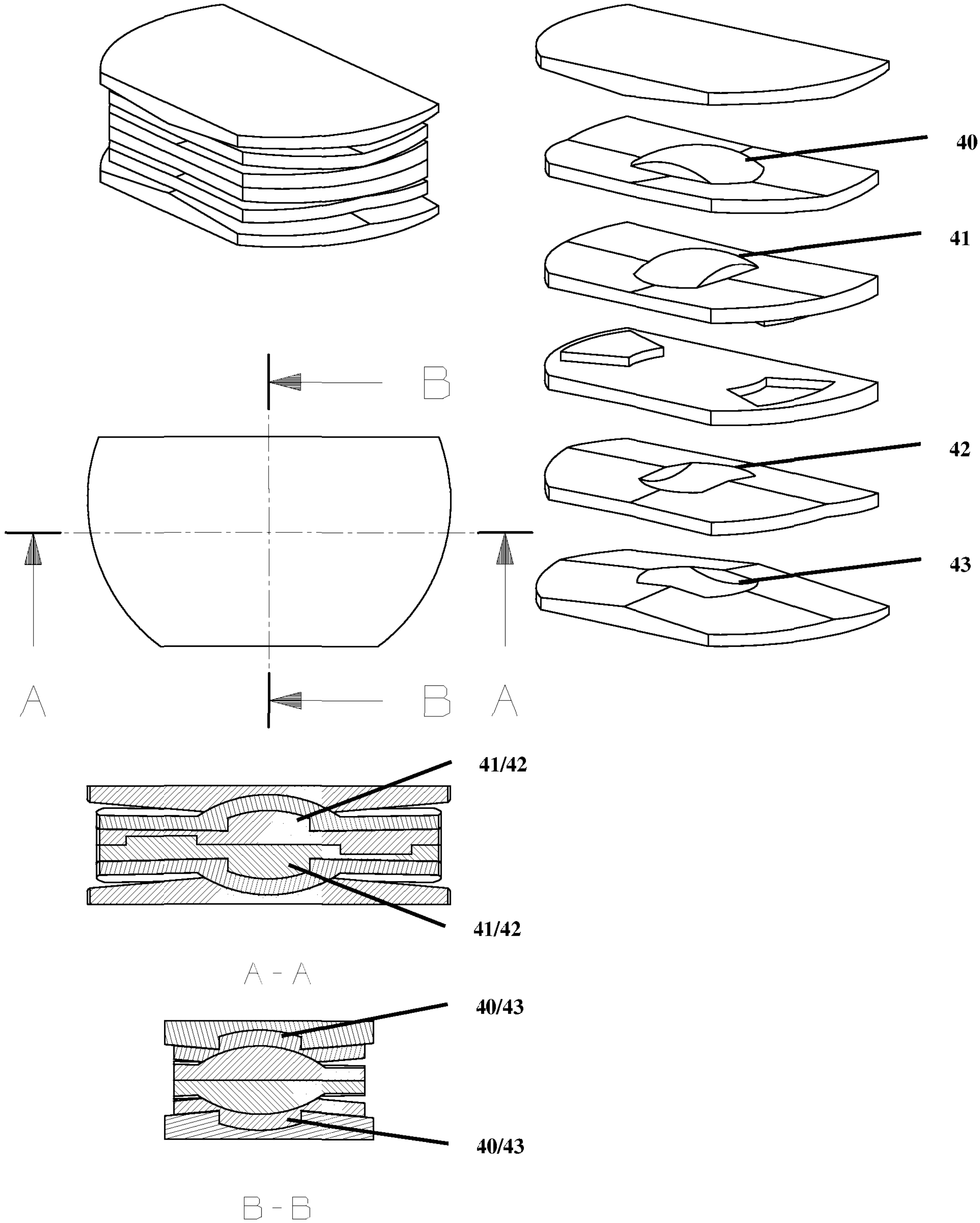


Fig. 9

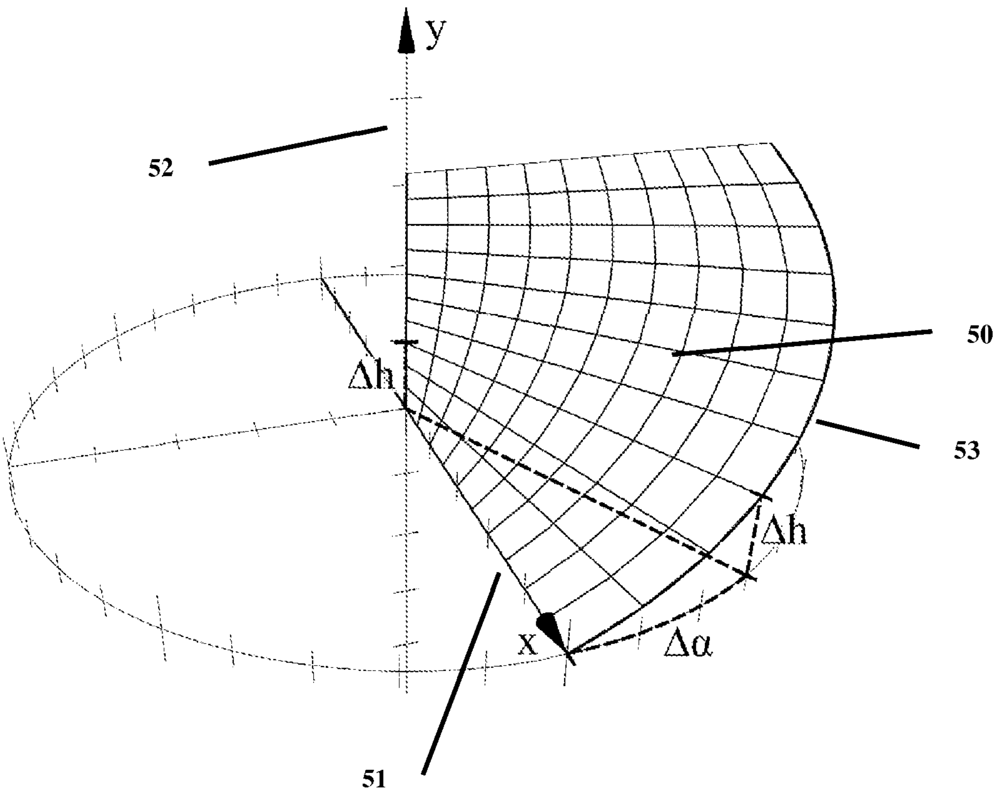
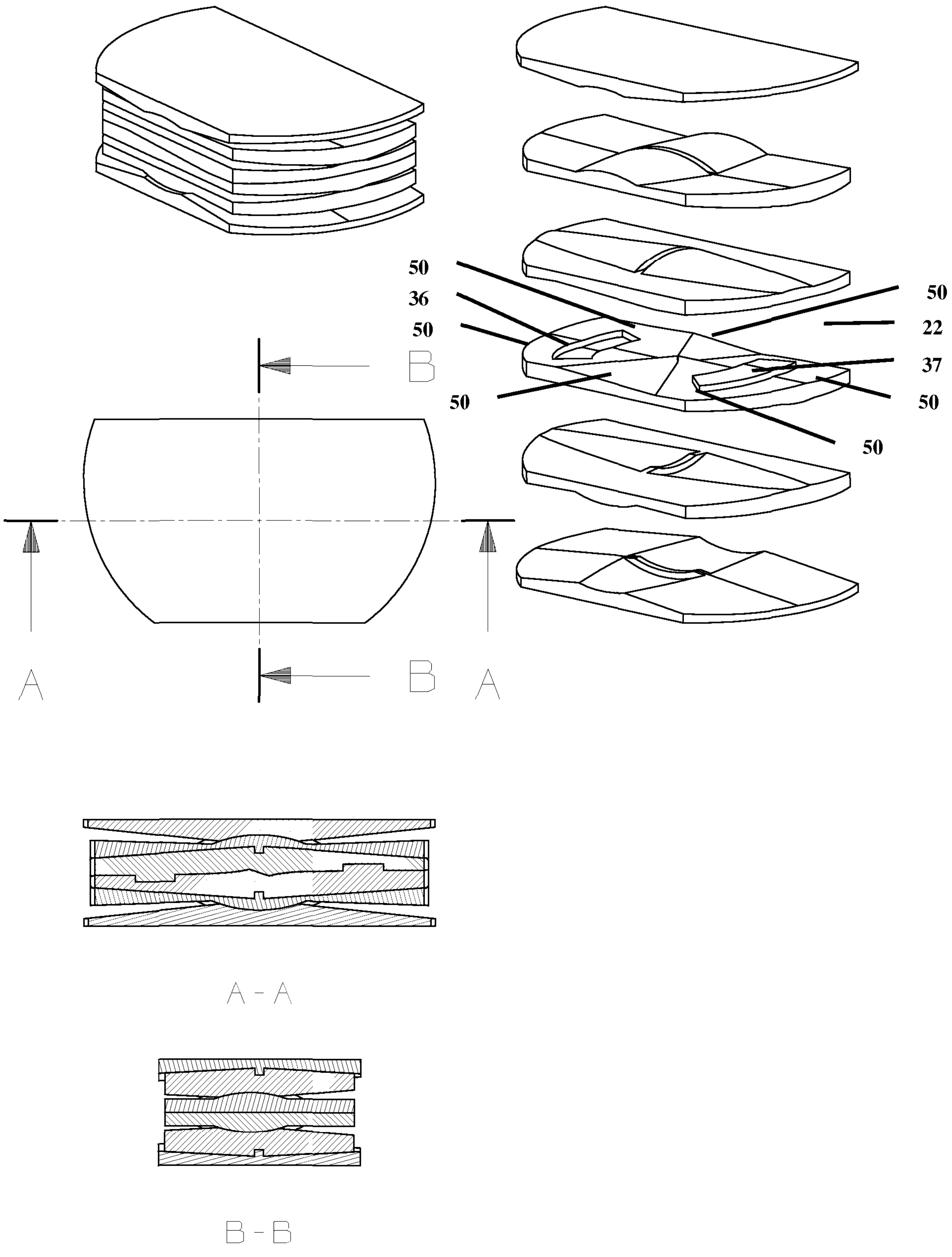


Fig. 10



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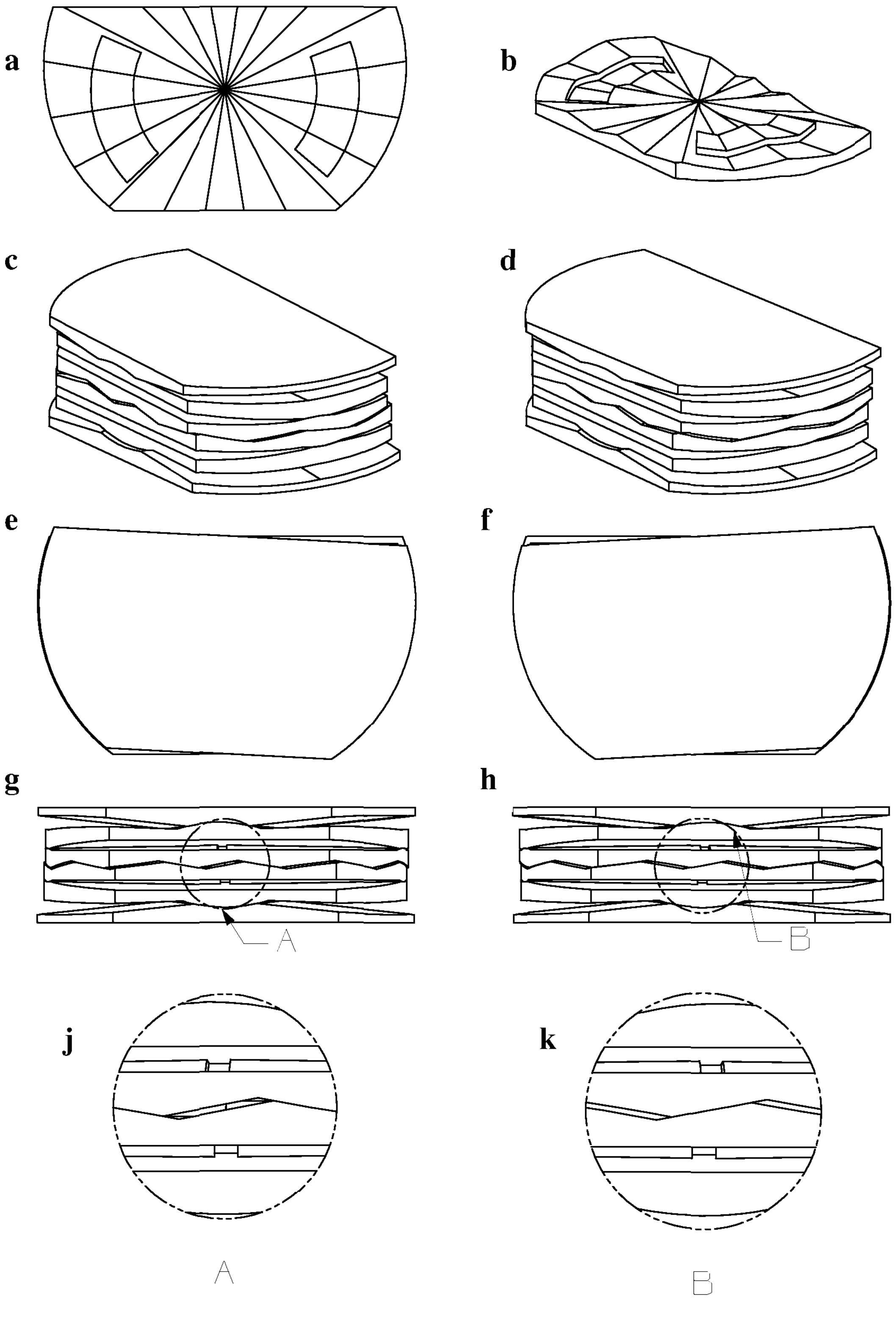


Fig. 12

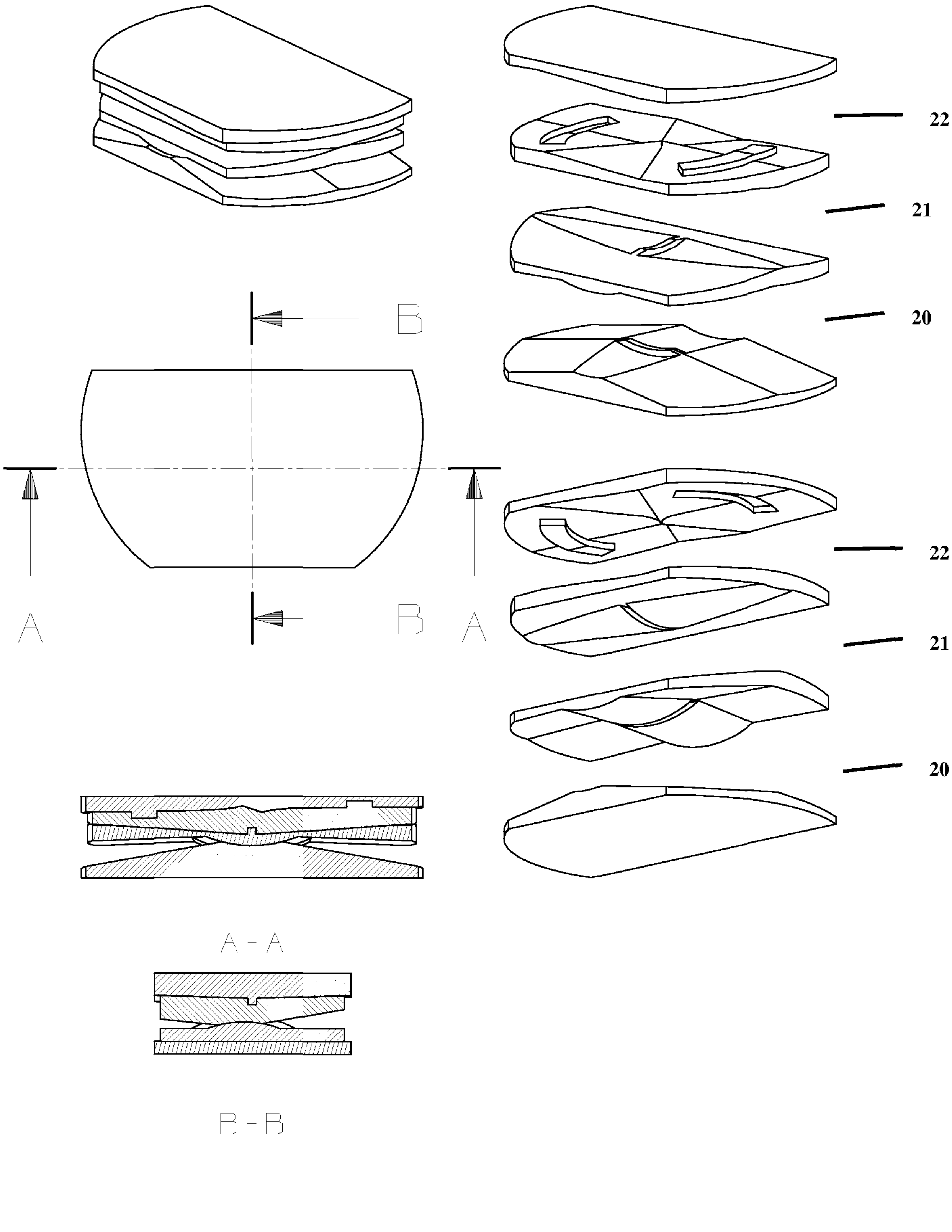


Fig. 13

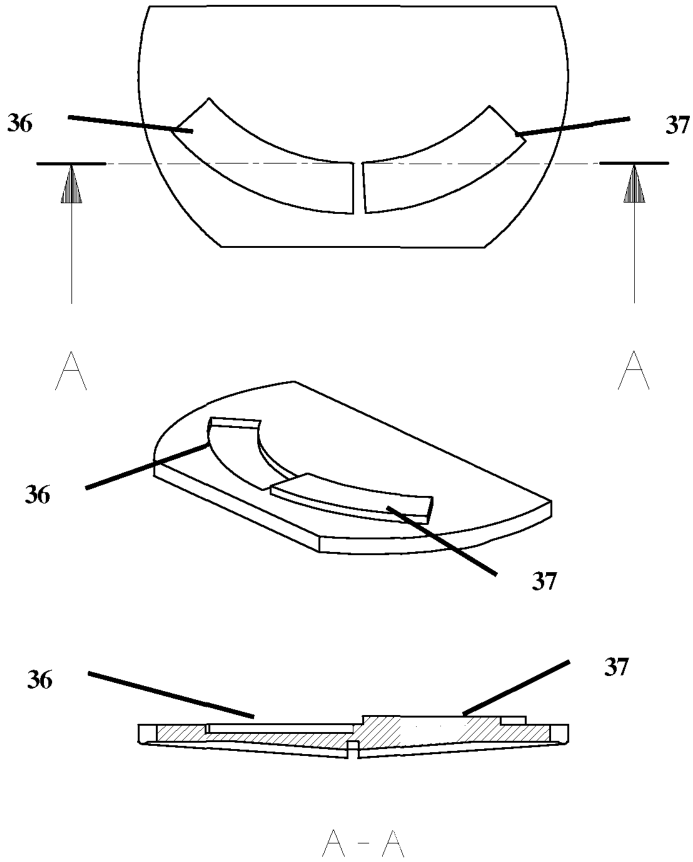


Fig. 14

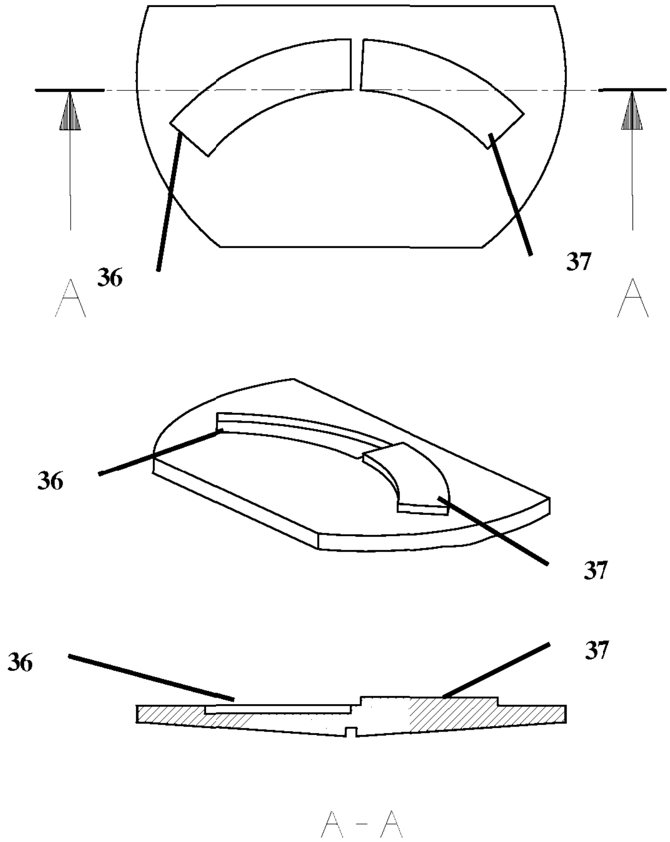
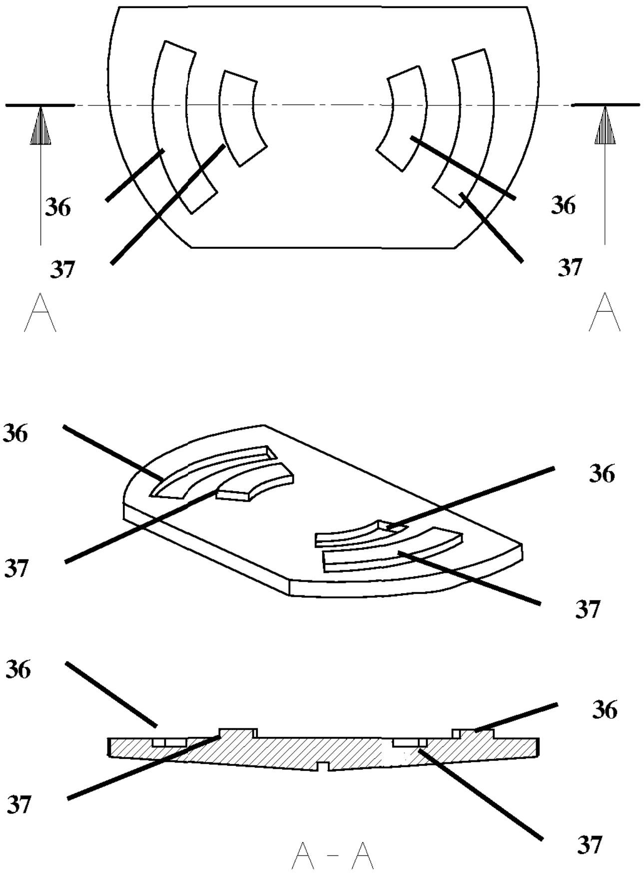


Fig. 15



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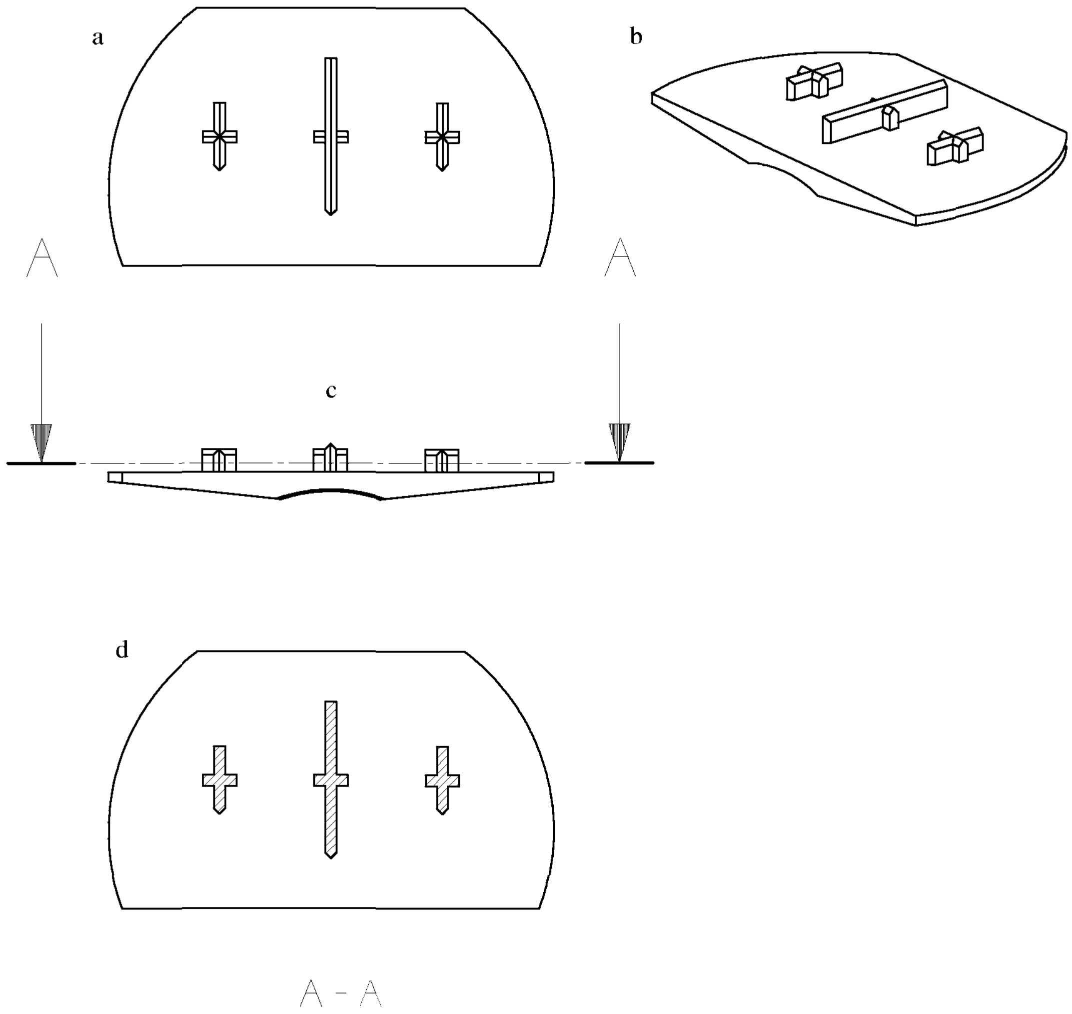

Fig. 17

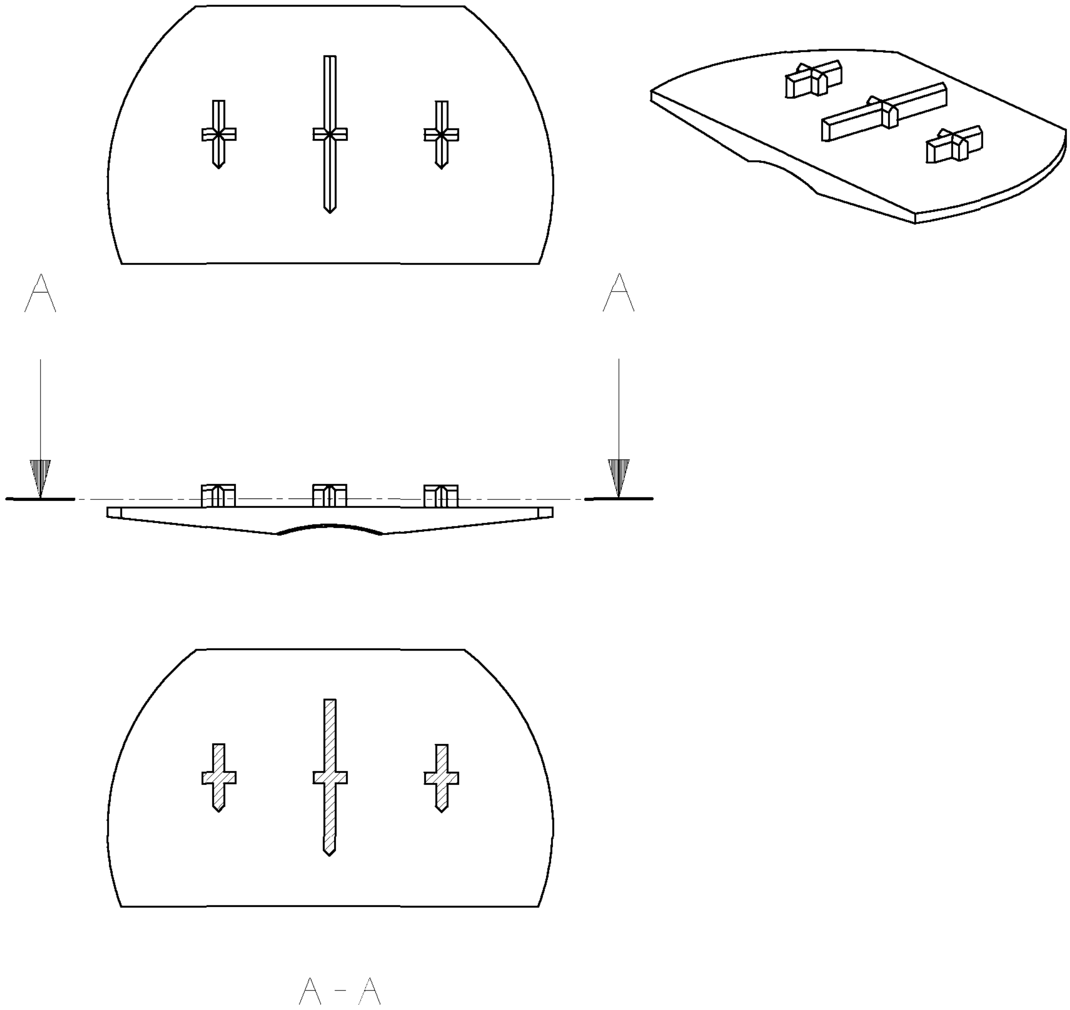

Fig. 18

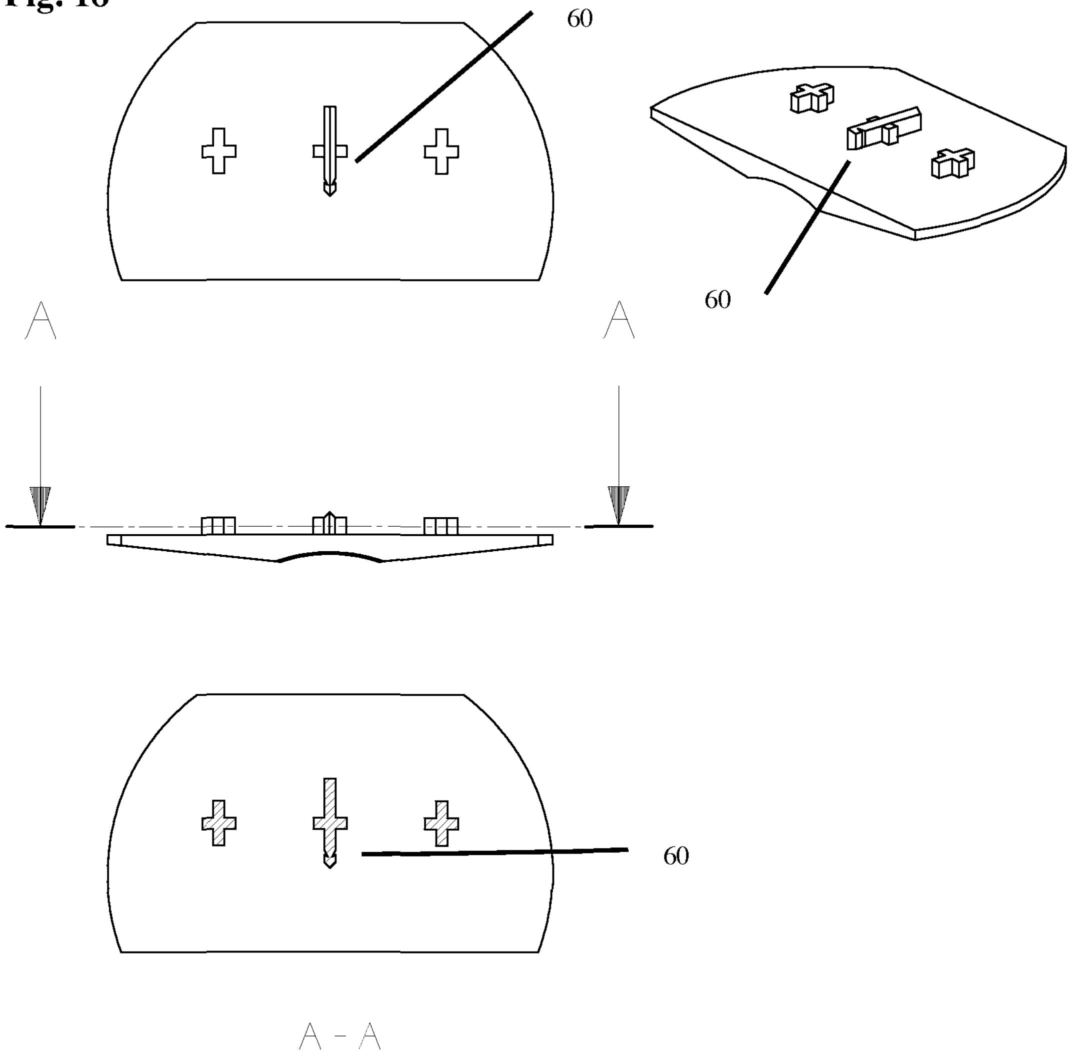

Fig. 19

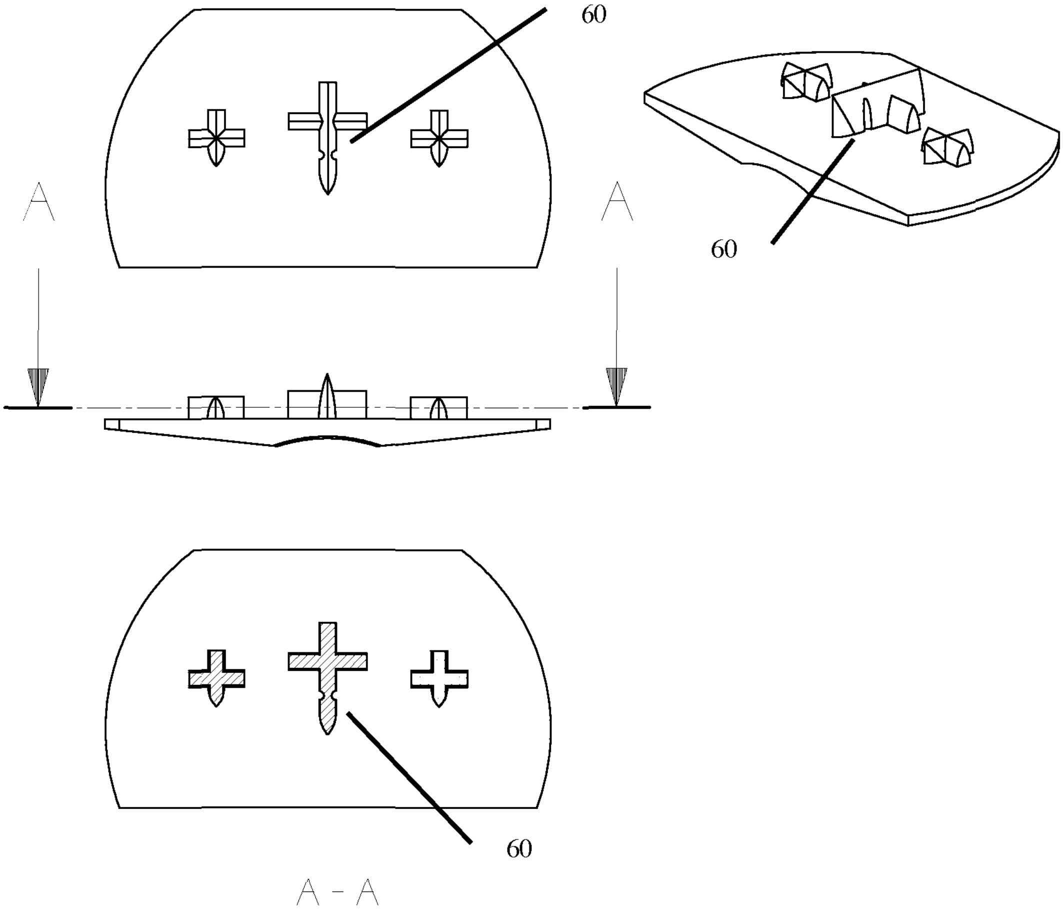

Fig. 20

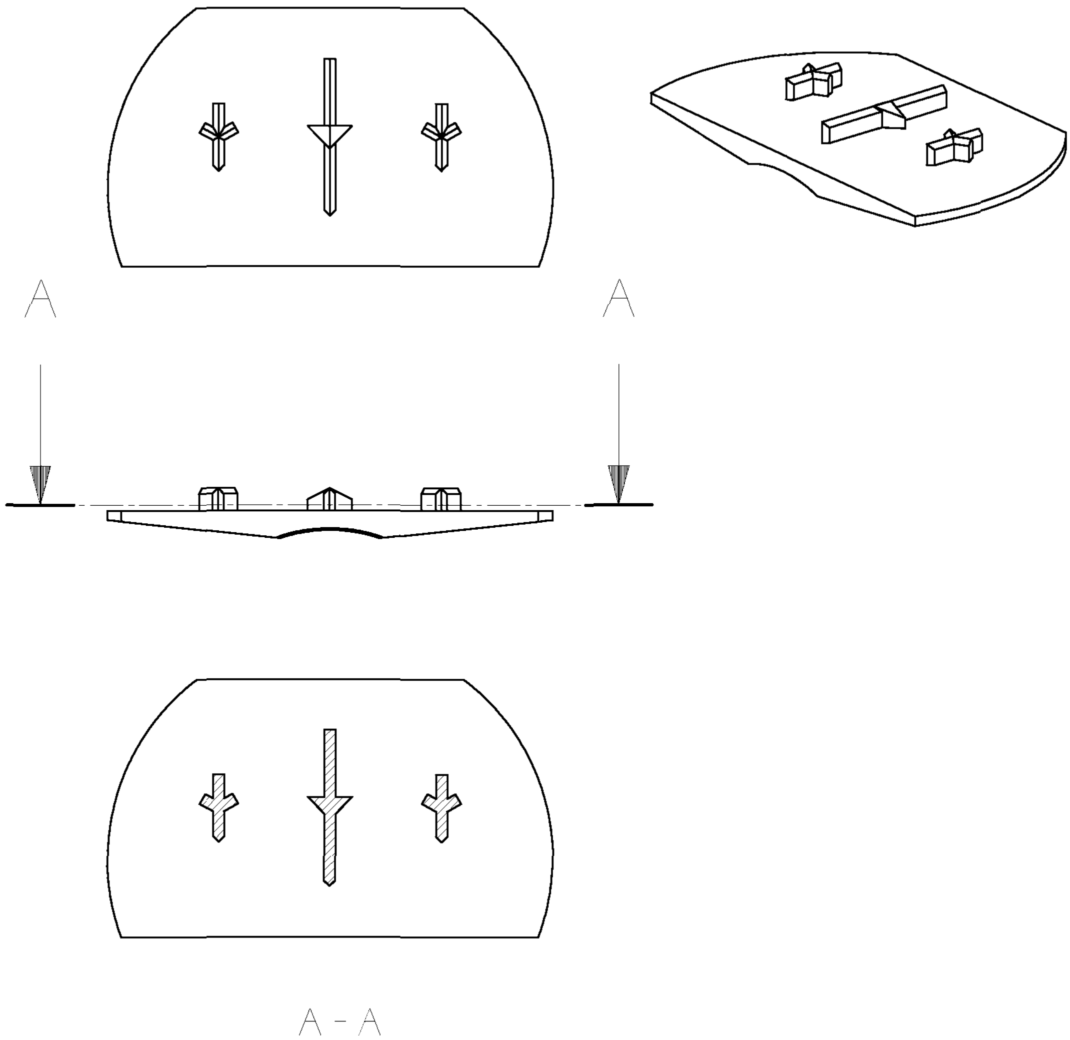

Fig. 21

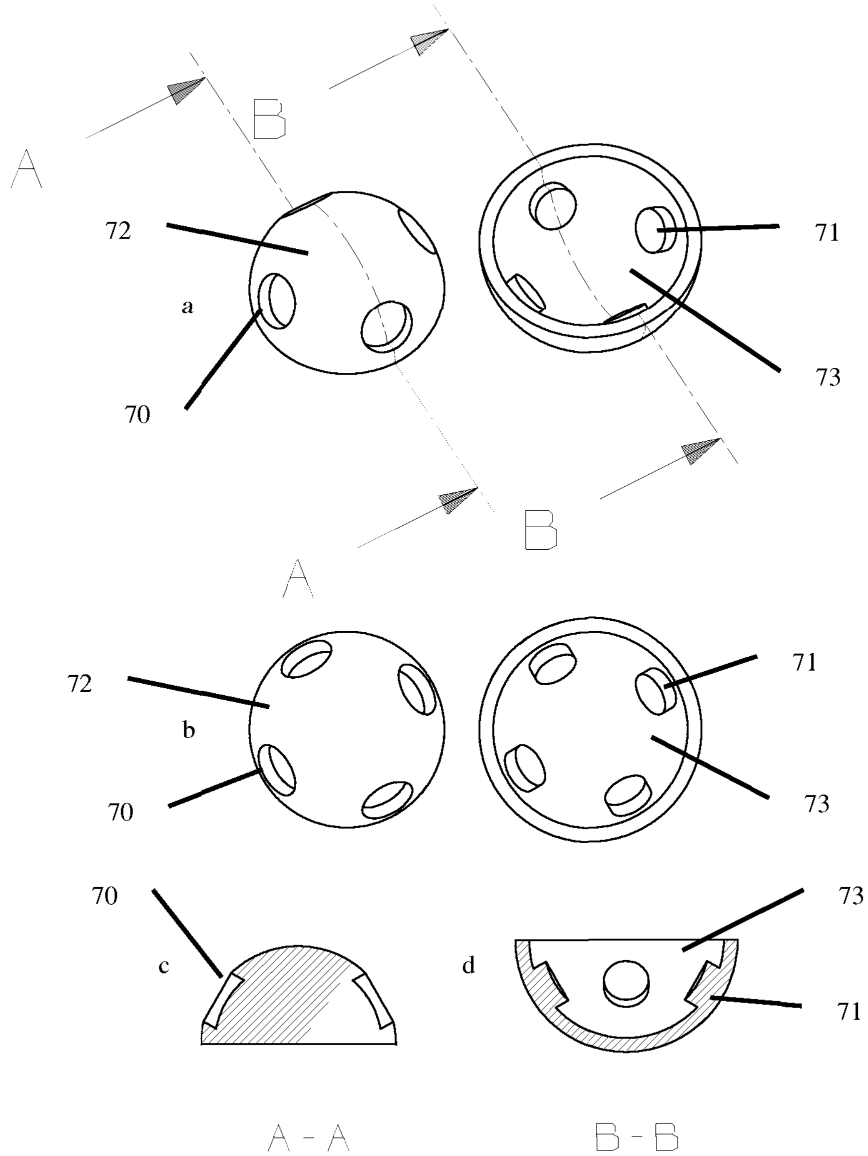

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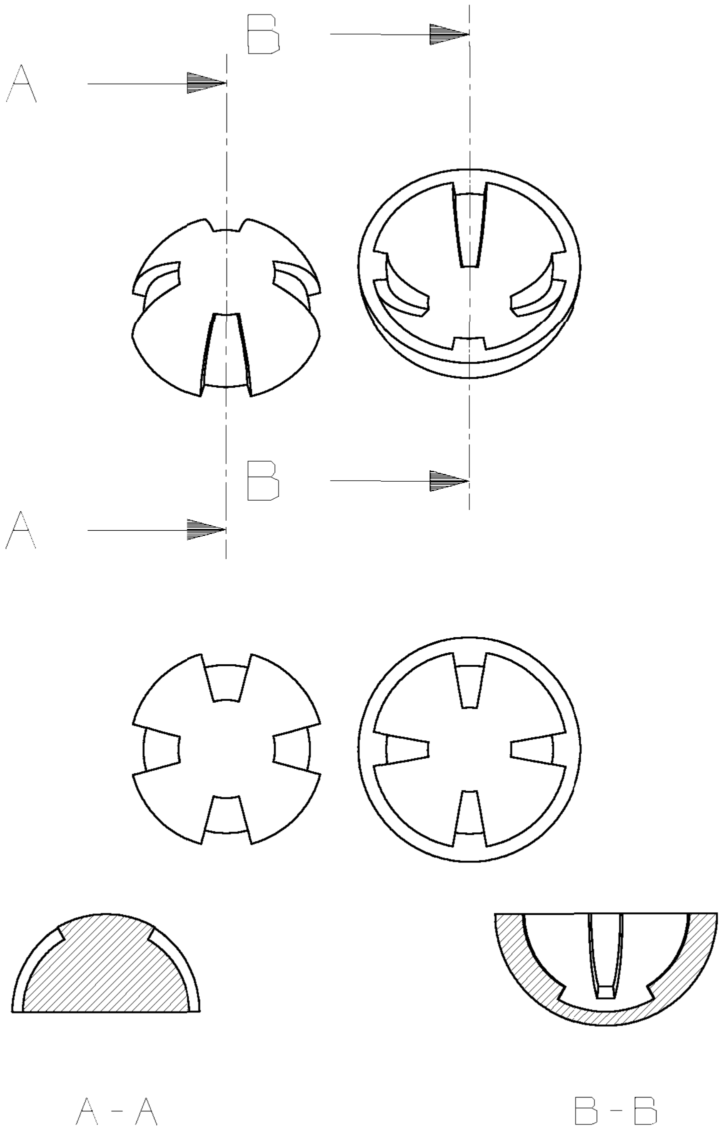
Fig. 22



Application No. GB0910613.9 RTM Date :15 October 2009

The following terms are registered trademarks and should be read as such wherever they occur in this document:

“PRODISC”, “FLEXICORE”, “MOBIDISC”, “KINEFLEX”, “XL-TDR”, “DYNARDI”, “INMOTION”, “PRESTIGE”, “MOBIC”, “DISCOVER”, “PCM”, “CERVICORE”, “M6”, “GALILEO”, “GRANVIA”, “NUNEC”, “BAGUERA”.

Modular prosthesis for cervical and lumbar spine

Description

FIELD OF THE INVENTION

The present invention relates to an intervertebral disc prosthesis for the total replacement of an intervertebral disc of the lumbar and cervical spine.

BACKGROUND OF THE INVENTION

The idea of function-retaining artificial replacements for intervertebral discs is younger than replacements of artificial joints of extremities, but nonetheless_about 50 years old [Büttner-Janz, Hochschuler, McAfee (Eds.): The Artificial Disc. Springer Verlag, Berlin, Heidelberg, New York 2003]. It is a response to biomechanical considerations, unsatisfactory results of fusion surgeries of the cervical or lumbar spine, disorders adjacent to fused motion segments and the development of new materials with greater longevity.

By means of function-retaining disc implants it is possible to avoid fusion surgery, i.e. to maintain, to restore or to improve the mobility within the intervertebral disc space. In an in-vitro experiment it is possible to achieve a normalization of the biomechanical properties of the motion segment to a large extent through the implantation of an artificial intervertebral disc after a nucleotomy.

Implants for the complete replacement of the intervertebral disc differ from those for the replacement of the nucleus pulposus; accordingly, implants for a total disc replacement are more voluminous. If a prosthesis for the total disc replacement is intended to cover the whole vertebral endplate, it is implanted via a ventral or lateral or anterolateral approach.

The indication for a function-retaining intervertebral disc replacement as an alternative to the surgical fusion includes, besides the painful discopathy, also pre-operated patients with a so-called post-discectomy syndrome, patients with a recurrent herniated intervertebral disc within the same segment and patients having painful pathology within the neighbouring intervertebral disc as a consequence of fusion surgery.

Presently, a total of nearly 30 different so called "total disc replacements" are clinically used for the function preservation of intervertebral discs. For the lumbar spine the CHARITÉ Artificial Disc, the PRODISC, the MAVERICK, the FLEXICORE, the MOBIDISC, the KINEFLEX; the ACTIV L, the XL-TDR, the DYNARDI, the PHYSIO-L and the INMOTION are particularly well known, and for the cervical spine the BRYAN, the PRESTIGE, the PRODISC-C, the KINEFLEX C, the MOBIC, the ACTIV C, the DISCOCERV, the DISCOVER, the PCM, CERVICORE, the M6, the GALILEO, the GRANVIA, the NUNEC AND the BAGUERA C..

There are different classifications of cervical and lumbar total disc replacements, according the number of articulation partners, biomechanical considerations and direct function-related conditions within the cervical as well as lumbar intervertebral space. At this time prostheses with two, one or no articulation surface are used. Depending on the number of functional partners and the material the prostheses have a fixed or mobile centre of rotation. Whereas prostheses with two sliding surfaces having a mobile centre of rotation are more physiologically designed, prostheses with only two functional related partners and one sliding surface are able to better stabilize the spine in multi-segmental implantations.

All prostheses for total disc replacements which are currently clinically used do not cover the complete function of the cervical and lumbar motion segment. The disc prostheses do not simulate the natural range of motion, only some disc prostheses include shock absorption to its function, but again without to simulate the segmental physiological range of motion. In longer term experience facet joint degeneration and disease may occur at same level as result of prosthetic hyper-mobility. So the original target of a disc replacement to painless or painfree stabilize the spinal motion segment by implantation a disc prosthesis is not yet fulfilled in the long run.

The common material for sliding partners is metal in combination with polyethylene; also well known are metal-to-metal bearing prostheses. Different sizes are achieved by the basis size of prosthetic plates, heights are achieved by the height of the prosthetic partners, and angles of lordosis are achieved by the angles of prosthetic partners.

The MAVERICK and the FLEXICORE for the lumbar spine are for example functionally a two-part prostheses with spherical convex-concave sliding partners, both with sliding partners made of metal. In contrast, for example the Mobidisc is functionally a three-part prosthesis with sliding partners of metal-polyethylene and two articulation surfaces. One area is a segment of a sphere, as it is in the two afore mentioned prostheses, with a convex and a concave surface of the articulating partners, each of the same radius, the other area of the Mobidisc being plane. Although a limitation of the axial rotation is planned within the plane section, it is not limited within the convex-concave area of articulation. In contrast the FLEXICORE has a small stiff stopping area within the spherical sliding surfaces limiting the rotation movement.

For example the BRYAN prosthesis and the M6 are clinically used as a compact prosthesis for total replacement of intervertebral discs of the cervical spine. It is attached to the vertebral bodies by titanium plates with a porous surface and achieves its biomechanical properties by virtue of polyurethane-polycarbonate.

The longest experience exists with the Charité prosthesis, which is the subject matter of DE 35 29 761 C2 and US 5,401,269 specifications. This prosthesis was developed in 1982 by Dr. Schellnack and Dr. Büttner-Janz at the Charité University Hospital in Berlin and was later on named SB Charité prosthesis. In 1984 the first surgery took place. The intervertebral disc prosthesis was further developed into model III and has been implanted worldwide (DE 35 29 761 C2, US 5,401,269) since 1987; it is still being used. Since 2008 additionally the Charité's further development named InMotion is being used. The prosthesis is functionally three-parted with the sliding partners being metal and polyethylene with two identical spherical sliding surfaces. On the one hand it has a transversally mobile biconvex polyethylene core and on the other hand the accordingly adapted concave cups within two metal endplates. For the adaptation to the intervertebral space, the Charité and InMotion prostheses provide different sizes of metal plates and different heights of size adapted sliding cores as well as angled prosthetic endplates, which when implanted vice versa in sagittal direction can also be used as replacement for the vertebral body. The primary fixation of the Charité and InMotion prosthesis is achieved by each six teeth, which are located in groups of three ventral and dorsal respectively on both sides lateral.

The other prostheses have other primary fixations on their surfaces directed towards the intervertebral bodies, e.g. other located and shaped teeth, a sagittal running keel, two sagittal keels in parallel or oblique to each other, or a structured convex surface, or crosswise running differently shaped recesses in combinations with ridges. Furthermore screw fixations can be used, either from ventral or from within the intervertebral space into the intervertebral body. To assure a long-term fixation of the prosthetic endplates to the intervertebral bodies and to thus generate a firm connection with the bone, coated surfaces were created in similitude to cement-free hip and knee prostheses. This direct connection between prosthesis and bone, without the development of connective tissue, makes a long-term fixation of the artificial intervertebral disc possible and reduces the danger of loosening or displacement of the prosthesis and material breakage.

One primary objective of function retaining intervertebral disc replacements is to closely adapt the motions of the prosthesis to the ones of a healthy natural intervertebral disc. Directly connected to this is the motion and stress for the facet joints at same level, which following inappropriate biomechanical stress have their own potential for disorders. There can be abrasion of the facet joints (arthritis, spondylarthritis), with a formation of osteophytes. As result of these osteophytes and also by a pathologic course of motion of the intervertebral disc alone, the irritation of neural structures is possible. Most important is the facet degeneration caused by non-physiological motion and load as a possible own pain generator in the long run after an artificial disc replacement of an originally painful degenerated disc at same level.

A healthy intervertebral disc is, in its interaction with other elements of the motion segment, composed in such a way that it allows limited motion, but not in comparison to different range of motion in extension and flexion as well as compared to rotation and lateral bending. For example, within the intervertebral disc, motion to the front and back is combined with rotational motion, and side motion is also combined with other motion directions. It is a matter of so called "coupled motion". The motion amplitudes of healthy intervertebral discs are very different, with respect to the extension (bending back) and flexion (bending forward) as well as to the lateral bending (right and left) and rotational motion. Although of common basic characteristics, there are differences between the motion amplitudes of the lumbar and cervical spine.

Due to a simultaneous translation movement of adjacent vertebrae, the center of rotation changes its position constantly in case of inconstant center of rotation. The prosthesis according to DE 35 29 761 C2 shows a construction which differs relative to other available types of prostheses which are build like a ball and socket joint and as a result move around a defined localized centre of rotation. By virtue of the three-part assembly of the prosthesis according to DE 35 29 761 C2, with two metallic endplates and the interpositioned freely mobile polyethylene sliding core, the course of motion of a healthy intervertebral disc of the human spine is mimicked as far as possible, however without the exact motion amplitudes in the specific motion directions.

A further important feature of the healthy lumbar intervertebral disc is its trapezium shape, which is primarily responsible for the lordosis of the lumbar and cervical spine. The vertebral bodies themselves contribute only to a minor extent to the lordosis. During prosthetic replacement of intervertebral discs the lordosis should be maintained or reconstructed. The Charité disc prosthesis provides four differently angled endplates, which moreover can be combined with each other. However, this surgery requires more surgical effort and has in case of needed change of prosthetic plates the risk of damaging the vertebral endplates which is associated with a danger of subsidence of the prosthesis into the vertebral bodies. If the adjustment of the lordosis is poor and an optimal load of the centre of the polyethylene core was not achieved, the prosthesis has to be removed completely. An overload of the facet joints is to avoid, for example caused by a hyperlordotic angle of the operated segment, because in the longer run a painful facet joint degeneration can be expected. A hyperlordotic disc space is a pre-condition for reduced segmental range of motion. The target prevention of the adjacent motion segment against disc degeneration can not be fulfilled.

There is no evidence of needed shock absorption within the spine to save tissue or specific anatomical structure; the facet joints are usually not horizontally loaded. The main function of shock absorption seems to be the need of motion within the disc space while at same time the natural disc doesn't have typical joint partners as ball and socket. By having the shock absorption of the disc the intervertebral angle can be changed without reducing the disc height at same time.

For the construction of an intervertebral disc prosthesis several aspects have to be taken into account: The level of the respective intervertebral space since the spatial conditions, the anatomy and biomechanical conditions differ significantly between the region of the cervical and lumbar spine. The protection of the facet joints shall be achieved at the index level of disc implantation and at the neighbouring levels. The disc degeneration and disorder at adjacent levels of artificial disc replacements should be avoided.

There is a need for an intervertebral disc prosthesis for the cervical and lumbar spine that enables physiological movement of high quality and quantity. The three-dimensional range of motion within the intervertebral space should mimic the coupled motion of a natural disc. In case of special anatomical and/or biomechanical local conditions or in revision surgeries a disc prosthesis is needed which doesn't allow motion in all directions postoperatively and a disc prosthesis for implantation via a lateral approach.

In case of any problem after total disc replacement, finally a fusion surgery is carried out, sometimes including removal of the disc prosthesis. Especially in disc prostheses with big keels for the fixation on the vertebral body the removal of the implanted and ingrown disc prosthesis leads to the need of bone removal at same time to make the explantation of the disc prosthesis possible. Depending on that a combined usable total disc prosthesis is needed for preservation of motion and for fusion surgery, without removal of the fixed prosthetic plates on the vertebral bodies.

SUMMARY OF THE INVENTION

The present invention provides an intervertebral disc prosthesis for the total replacement of the intervertebral disc within the cervical and lumbar spine, comprising an upper module adapted to firmly assemble with an upper vertebral body, a lower module adapted to firmly assemble with a lower vertebral body, and four middle modules located between the upper and lower module, wherein adjacent modules articulate with each other by their facing surfaces, defining an articulation surface, and wherein an articulation surface comprises at least one protuberance on one module corresponding with at least one recess on the adjacent module for articulation with the protuberance, and each protuberance and recess being surrounded by an edge, and wherein the corresponding protuberance and recess are constructed in such a manner that two adjacent modules can only rotate around either a sagittal, or a frontal, or a transversal axis, and wherein the maximal degree of rotation permitted by a single articulation surface is limited by the height and shape of its protuberance and corresponding recess and their respective edges, and wherein at maximal rotation in each direction of the sagittal, frontal and transversal axis, the surrounding edges of the corresponding modules have a two-dimensional surface contact.

The rotation along one axis is limited or defined by at least one articulation surface. This means that one articulation surface can only rotate around one axis, but that more than one articulation surface can rotate around the same axis.

The three rotation axes shall be angled with 90 degrees to each other as the x-, y- and z-axis in a coordinate system. It is further intended that at least one rotation axis has a different angle than 90 degrees with respect to at least one of the other rotation axes and at least two rotation axes have no intersection point. This means that the rotation axes for rotation around sagittal and frontal axes are not necessarily in the same horizontal level.

The protuberance and corresponding recess of at least one articulation surface of two adjacent modules can be completely surrounded by an edge. This is especially the case for the articulation surface defining the rotation around the transversal axis, where the edges can be plane and surround the protuberance(s) and recess(es) completely.

Since the prosthesis has a modular assembly at least two modules shall be exchangeable by a single module or a single module can be exchangeable by at least two modules. It is also intended that the middle modules are removable. A prerequisite for this is that the surfaces of modules that are part of the resulting new articulation surface have a corresponding protuberance and recess as well as corresponding edges.

Two adjacent modules can be firmly, but reversible assembled to each other, either allowing or preventing a rotation around the respective axis. Alternatively two adjacent modules can be firmly assembled two each other without any rotation around the respective axis. In this case any space between the surfaces of the modules of an articulation surface can be filled. It is also intended that a module is replaced by a module that has on at least one side a negative copy or shape of the facing surface of the adjacent module so that any rotation is impossible.

The edge of the articulation surface for the axial rotation around the transversal axis shell comprise at least two sub-surfaces with alternating gradients for soft limitation of rotation around the transversal axis. A sub-surface represents a part of the edge of the respective articulation surface. The height of the edge can increase or decrease via the alternating gradients of the sub-surfaces.

All articulation surfaces together can determine mono-directional, bi-directional or three-directional motion or a coupled motion thereof around the sagittal, frontal and/or transversal axis. This means that although each articulation surface is only responsible for the rotation around one axis, the rotation around different axes at different articulation surfaces may result in a coupled motion.

It is further intended that only rotation around two axes is possible, preferably around the sagittal and transversal axis.

Each module can be constructed in one piece or firmly, but reversibly assembled of at least two pieces. Protuberance or recess may represent parts that are assembled with the rest of the module, so that it is possible to combine different materials or differently coated surfaces.

Protuberance and recess can have a spherical, cylindrical, torus-like and/or cone-like shape or a combination thereof and protuberances and corresponding recesses can have identical or different radii. Basically all combinations of geometric shapes or forms can be used including all kinds of bodies of revolution.

For the articulation surface for the rotation around the transversal axis different shapes may apply in order to achieve a soft limitation of rotation around the transversal axis. This comprises at least two separate helices that can be shifted towards each other for soft limitation.

To achieve a limitation of rotation around at least one axis, protuberances and recesses can have groove-and-tongue joints for the limitation of the range of motion of adjacent modules against each other. A tongue-and-groove joint may also be suitable to avoid dislocation of adjacent modules to each other.

The fixation of the upper and lower module on?? each neighbouring vertebral body is important to avoid short or long term module or prosthesis dislocation.. It is intended that upper and lower module have on their outer sides for assembly with a vertebral body combined sagittally and frontally orientated webs, preferably at least one cross-shaped anchor, optionally in combination with anchoring teeth. The webs of the cross-shaped anchor can be pointed in order to facilitate sinking into the vertebral body.

To facilitate implantation of the prosthesis within the intervertebral space it is intended that the cross-shaped anchor and/or the webs of the upper and lower module for assembly with a vertebral body are itself means or can have means for an instrument to hold the prosthesis during im- or explantation

The center of rotation of the transversal axis is determined by the position and/or shape of protuberance and recess of the articulation surface. Thus it is possible to adjust the centre of rotation to the needs of the patient receiving the prosthesis, depending on the anatomical direction of the facet joints and its angle to each other, to include these joints to the circle of segmental axial rotation of the cervical or lumbar spine.

DETAILED DESCRIPTION OF THE INVENTION

The prosthesis provided by the invention is intended for primary total disc implantations with coupled physiological motion within the disc space as well as for fused fixation of a painful or unstable disc, depending on the kind of inserted prosthetic modules. The modular prosthesis is also intended for revision surgeries via a lateral approach, including after disc replacements, by insertion a complete modular prosthesis or modules of it, if needed without for example lateral bending postoperatively.

The modules of the prosthesis according to the present invention are exchangeable representing the modular character of prosthesis according to the invention. The prosthesis may comprise at least three articulation surfaces for each rotational axis in order to allow a coupled motion. Furthermore the modules can be chosen so that only rotation around two or only one axis is possible. Finally modules can be chosen that no more rotation is possible resulting in a fusion of the adjacent vertebral bodies.

With respect to the presented invention three cutting planes shall be defined by the following terms: A "sagittal section" or a "sagittal view" describes a view from lateral, because the cutting plane runs vertically from the front to the back or vice versa. The term "frontal" is synonymous with "ventral" and the term "back" with "dorsal". A "frontal section" or the "frontal view" is a vertical section from the right lateral side to the left lateral side or vice versa. The term "lateral" stands for sidewise and laterolateral means from the right side to the left side or vice versa. Sagittal and frontal sections are vertical sections as they both run in a vertical plane from cranial to caudal or vice versa, but rotated at 90 degrees from each other. A view in the "transversal plane" or a "transversal section" shows a top-view onto the prosthesis or the cutting plane or the endplate of a vertebral body, as it is a horizontal section.

The three spatial x-, y- and z-axis shall be defined as "sagittal rotation axis" for extension and flexion function within the disc space, as "frontal rotation axis" for the bending function to right and left side of the disc space and as "transversal rotation axis" for the right/left rotation, meaning the rotation around the vertical axis running in craniocaudal direction.

Both, cutting plane or a rotation axis can be located centrally, laterally, dorsally, ventrally, caudally or cranially. Additionally cutting planes and rotation axes can be bent to each other.

The word module designates in the context of the present invention a sliding partner or a part of the prosthesis with an upper and lower sliding surface. The modules at the top and bottom are designated as upper and lower module as they are arranged at the ends of the disc prosthesis and they are intended for fixation at the neighbouring vertebral bodies. Depending on that task the upper and lower module have only one sliding surface.

Two-dimensional surface contacts refer to two surfaces that come in contact as they have corresponding shapes so that not only punctual or linear contacts take place. This means that a surface does not have to be plane, but shall also have a curved form or a combination thereof as long as a two-dimensional contact of the surfaces will be achieved at rotation around the respective axis, including at maximal possible rotation.

With respect to the description and depiction of the presented invention an articulation area or surface as well as an articulation designates facing surfaces of adjacent modules which come into contact or articulate with each other. A articulation surface comprises a protuberance on the surface of one module and a corresponding recess on the facing surface of the adjacent module as well as an edge on at least one surface. The term articulation surface is synonymous with the term sliding area. The term "corresponding", with respect to articulation sliding surfaces designates not only congruent protuberances or recesses articulating with each other, but also may comprise convex and concave shaped surfaces articulating with each other, and moreover this term also designates articulation surfaces with its protuberances and recesses that are not completely congruent. Such "deviations" or tolerances regarding the articulation surfaces of articulating modules can be caused on the one hand by the chosen materials and shapes. On the other hand it may also be intended that protuberance and recess articulating with it are not totally congruent, for instance in order to define the maximal possible rotation or motion of the articulating modules directly. Protuberance or recess can be also designated as convexity or concavity.

Since the number of the three axes of rotation corresponds to the minimal number of three articulation directions, the prosthesis according to the present invention provides the possibility to limit or define the rotation around each axis by one articulation. Thus, the shape or design of each articulation surface has only to be adapted to the physiological conditions with respect to one of a dorsoventral, laterolateral or right/left kraniokaudal direction and is independent on the shape or design necessary to define the rotation around another or both other axes.

An edge, as per the invention, indicates an area located between outer rim of the respective module and its protuberance or recess. An edge surrounds the protuberance or recess completely or partly. The edges of the respective modules run horizontally and/or at an incline and have a plane or curved or angled surface. It is essential for the shape of the surfaces of the edges, that during terminal inclination of the modules towards each other a gap-closure across a maximally possible area between the edges of the modules is achieved. Should the edges not have a plane surface, they have in any case to be designed in such a way that during gap-closure, a maximally possible two-dimensional contact arises between them. It is intended that an edge may be plane or bent or comprise a sector of a cone or a torus.

A spherical ball-and-socket joint has no limitation regarding the vertical or axial rotation with respect to the two parts of the joint, but such a joint provides good premises for an optimal uptake of pressure during a gap closure of two-dimensional facing surfaces of two adjacent modules at terminal inclination or rotation. It is possible to design a ball-and-socket joint preventing the unlimited rotation around the vertical axis and only allowing a rotation around one axis by integration of groove-and tongue-joints. Besides this a spherical protuberance is not necessarily a hemisphere but can be a derived from a hemisphere by vertically cutting at two opposing sides.

As a prosthesis according to the present invention allows the definition of maximal rotation around one of the three axes at a single articulation surface it is possible to use corresponding hemispherical protuberances and recesses as convexity or concavity and combine their design with the shape or design of a surrounding edge to achieve two-dimensional contacts during terminal inclination or rotation around an axis instead of spot wise or linear contacts. That results in articulation specifically adapted to the needs for limiting the rotation around one axis independent on the needs of one or both other axes.

The limitation of rotation around the three axes can be distributed to different articulation surfaces. It is additionally possible to distribute the limitation or rotation of one axis to more than one articulation surface, for example to limit the motion to dorsal direction by another articulation surface than the ventral rotation around the same axis It is also intended that the limitation in one direction of the three axes can be achieved by two articulation surfaces, e.g. the rotation in dorsal direction is limited by two different articulation surfaces.. Consequently a disc prosthesis according to the present invention provides maximal flexibility for adapting the physiological range of motion of the whole prosthesis that shall result in combined movements or coupled motion adapted to the needs of the patient's spinal motion segment. By this it is possible to achieve long term results without side effects like stress for the facet joints following inappropriate biomechanical stress having their own potential for disorders. Abrasion of the facet joints (arthritis, spondylarthritis), in the full blown picture, with a formation of osteophytes will be prevented and osteophytes and also the irritation of neural structures. Depending on the the position and/or shape of protuberance and recess of the articulation surface the location of centre of rotation of the transversal axis is defined. Thus it is intended to include the facet joints to the circle of craniocaudal axial rotation of the spinal segment, to protect the facet joints also during axial rotation to the right and left side.

In order to achieve the already mentioned two-dimensional surface contact the edge surrounding protuberances and recesses plays an important role. A further non-limiting advantage of an intervertebral disc prosthesis, as per the invention, is that, in certain embodiments, in addition to its approximated angles of motion, which come close to the natural degrees of motion, the rotation is limited softly by plane contact areas.

The present invention provides a modular prosthesis that can be adapted ahead of the implantation by choosing the appropriate middle sliding modules from a set of existing modular parts.

It is further intended that the surfaces of at least two adjacent sliding partners are firmly but reversible fixed to each other. These measures serve to prevent the rotation around at least one axis or prevent partly the rotation around one axis and can be used to prevent any rotation resulting in a fusion of adjacent intervertebral bodies. In case of revision surgery the upper and lower module can stay in place, but the middle modules can be changed for further motion retaining function or if needed for fusion of the spinal segment. If the revision surgery is carried out via a lateral approach new modules can be implanted for allowing motion to dorsal and ventral direction as well as craniocaudal axial rotation, but no lateral bending is possible to avoid a frontal angled disc space.

It has to be noted that the modular properties of the intervertebral disc prosthesis according to the invention relate to modules that can be used within a single total disc prosthesis to achieve optimal adaptation, but do not relate to different prostheses.

BRIEF DESCRIPTION OF THE FIGURES

The invention will be described by figure without being limited to the shown embodiments, the figures show:

Fig. 1	Different views of a six-part intervertebral disc prosthesis
Fig. 2	Illustration of the rotation around a transversal axis
Fig. 3	Illustration of rotation around a frontal axis
Fig. 4	Illustration of rotation around a sagittal axis
Fig. 5	Representation of different coupled rotations
Fig. 6	Prosthesis with spherical protuberances and recesses
Fig. 7, 8	Variation of the six-module prosthesis depicted in Fig. 6

DETAILED DESCRIPTION OF THE FIGURES

Figure 1 shows different views of a six-part intervertebral disc prosthesis. Fig. 1a shows a spatial view of the assembled prosthesis. An explosion view of the same prosthesis is shown in Fig. 1b. Fig. 1c shows a top view of the prosthesis, Figs. 1d and 1e depict section views corresponding to the section lines of Fig 1c.

The six vertically stacked modules of the prosthesis form a total of five articulation surfaces. Except for the two outer modules, all modules participate in two articulation surfaces. The outer surfaces of the two outer modules that are not part of an articulation surface are in contact with adjacent vertebrae after implantation. The upper three modules are identical to the lower three modules. The lower three modules are obtained by rotating the upper three modules by 180° around a sagittal or transversal axis.

The five different articulation surfaces are grouped into three different types. Each articulation surface is constructed in such a way, that it permits only rotation around a single axis. The outer articulation surface 20 permits rotation around a frontal axis, the articulation surfaces 21 around a sagittal axis and the middle articulation surface 22 around a transversal axis. The convex (30, 31) and concave (32, 33) surfaces of the articulation surfaces are constructed by using surfaces of right circular cones. As the same conical surfaces are used for constructing the convex and concave portions of a single articulation surface, there is perfect two-dimensional contact between the convex and concave portions. The guidance grooves 34 and corresponding guidance rails 35 prevent any translation. The middle articulation surface 22 consists of two planes whose movement is constrained by guidance grooves 36 and rails 37 in such a way, that the planes can only rotate around a transversal axis. At maximum rotation of the articulation surfaces 20 and 21, the edges that are next to the convex and concave surfaces get into perfect two-dimensional contact, thus stopping any further rotational movement. The maximum rotation permitted by the middle articulation surface 22 is constrained by its guidance grooves and rails 36 and 37.

Figure 2 illustrates the rotation around a transversal axis permitted by the six-module prosthesis. Figs. 2a and 2b show spatial views of maximum rotations in the two possible directions. Figs. 2c and 2d show corresponding top views and Figs. 2e and 2f contain section views corresponding to the respective section lines of Figs. 2a and 2b. The section views of Figs. 2e and 2f show the interaction of the guidance grooves 36 and rails 37 during rotation around a transversal axis. As the guidance grooves 36 are smaller than the guidance rails 37, they permit a limited amount of rotation. The centre of rotation lies in the centre of the concentric circle segments that are used for constructing the guidance grooves 36 and rails 37. At maximum rotation, the small gap between the guidance groves and rails is closed, thus preventing any further rotation.

Figure 3 shows the rotation around a frontal axis permitted by the six-module prosthesis. Figs. 3a and 3d show spatial views of maximum rotations in the two possible directions. Figs. 3b and 3c show frontal and sagittal section views of Fig. 3a respectively. Fig. 3e contains a frontal section view of Fig. 3d. As can be seen in the section views, the edges of the adjacent rotating modules touch at maximum rotation, forming perfect two-dimensional contact areas which prevent any further rotation.

Figure 4 shows the rotation around a sagittal axis permitted by the six-module prosthesis. Figs. 4a and 4d show spatial views of maximum rotations in the two possible directions. Figs. 4b and 4c show frontal and sagittal section views of Fig. 4a respectively. Fig. 4e contains a sagittal section view of Fig. 4d. As can be seen in the section views, the edges of the adjacent rotating modules touch at maximum rotation, forming perfect two-dimensional contact areas which prevent any further rotation.

Figure 5 depicts different coupled rotations of the six-module prosthesis. Fig. 5a shows a combined lateral flexion and extension, Fig. 5b a lateral flexion, Fig. 5c a combined lateral flexion and flexion, Fig. 5d extension, Fig. 5e neutral position, Fig. 5f flexion, Fig. 5g combined lateral flexion and extension, Fig. 5h lateral flexion, Fig. 5j combined lateral flexion and flexion, Figs. 5k and 5m: axial rotations.

Figure 6 shows a variation of the construction of the convex and concave surfaces of Fig. 1. Instead of conical surfaces, spherical surfaces are used for the construction of the different convexities (30, 31) and concavities (32, 33). Furthermore, there are three guidance grooves 34 and rails 35 per articulation surface, instead of just one.

Figure 7 shows a variation of the six-module prosthesis depicted in Fig. 6. Instead of three guidance grooves and rails or tongues per articulation surface, there are only two of each.

Figure 8 shows another variation of Fig. 6. There are no explicit guidance grooves and rails. Instead, the concavities (42, 43) and convexities (40, 41) are constructed in such a way that they form guidance grooves and rails themselves.

Figure 9 illustrates the definition of a helical surface 50. A helical surface is obtained by rotating a continuous curve 51 around an axis 52 and translating it along this axis at the same time. At any time during this process, the quotient $\Delta h/\Delta\alpha$ (Δh denoting the amount of translation and $\Delta\alpha$ denoting the amount of rotation) must be constant. The surface that the continuous curve passes through during this combined rotation and translation defines the helical surface. The constant quotient $\Delta h/\Delta\alpha$ defines the slope of the helical surface. In this figure, the continuous curve 51 is a straight line. However, more complex shapes such as arcs and combinations of lines and arcs could be used as well. The helical surface is said to be clockwise if the helix 53, which forms its outer rim, is clockwise, and the helical surface is said to be counter clockwise if its rim is counter clockwise.

Figure 10 shows a variation of Fig. 1. Instead of simple planes, six alternating clockwise and counter clockwise helical surfaces 50 as described in Fig. 9 have been used for constructing the articulation surface 22. That is, the planes – also those at the bottom of the guidance grooves 36 and on top of the guidance rails 37 – have been replaced by those six helical surfaces.

Figure 11 shows the effect of the alternating helical surfaces as described in Figs. 9 and 10 on rotation around a transversal axis. In order to make the effect more visible, 20 alternating clockwise and counter clockwise helical surfaces are shown in this figure. Fig. 11a shows a top view of a prosthesis module with helical surfaces. Fig. 11b shows the same module in a spatial view. Figs. 11c and 11d show the entire six-module prosthesis in positions of maximum rotation around a craniocaudal axis. Figs. 11e and 11f show top views of Figs. 11c and 11d respectively, and Figs. 11g and 11h show corresponding front views. Finally, Figs. 11j and 11k show detail views as indicated in Figs. 11g and 11h. As can be seen in Figs. 11j and 11k, by using alternating clockwise and counter clockwise helical surfaces, the upper and lower halves of the prosthesis are driven apart when they are rotated against each other around a craniocaudal axis. Thus, the height of the whole prosthesis increases during such rotations, no matter in which direction the rotations occur. The idea behind this mechanism is to have a softer rotational limit.

Figure 12 shows a variation of Fig. 10. Instead of a six-module prosthesis, Fig. 12 depicts a four-part prosthesis. While the prosthesis shown in Fig. 10 has two articulation surfaces allowing rotations around a transversal axis and two articulation surfaces allowing rotations around a sagittal axis, the four-module prosthesis shown in this figure has only a single articulation surface for each of the two axes. This makes it possible spare two articulation surfaces and thus two modules while still allowing the same amount of rotation around the transversal and sagittal axes. Another possibility to construct a similar four-part prosthesis would be to reorder the different articulation surfaces 20, 21 and 22 in such a way that articulation surface 22 becomes the middle articulation surface (not shown).

Figure 13 shows a variation of the articulation surface for rotations around a transversal axis. The centre of the concentric circle segments that are used for constructing the guidance grooves 36 and guidance rails 37 does no longer lie within the bounds of the prosthesis. Instead, the centre has been moved dorsally, out of the prosthesis. This effectively means that the transversal axis around which all rotations in this articulation surface occur, has been moved dorsally, out of the prosthesis. This concept of a dorsal axis of rotation can be combined with the concept of helical surfaces which has been described in Figs. 9, 10 and 11 (not shown).

Figure 14 shows a variation of the articulation surface for rotations around a transversal axis. The centre of the concentric circle segments that are used for constructing the guidance grooves 36 and guidance rails 37 does no longer lie within the bounds of the prosthesis. Instead, the centre has been moved ventrally, out of the prosthesis. This effectively means that the transversal axis around which all rotations in this articulation surface occur, has been moved ventrally, out of the prosthesis. This concept of a ventral axis of rotation can be combined with the concept of helical surfaces which has been described in Figs. 9, 10 and 11 (not shown).

Figure 15 shows a variation of the articulation surface for rotations around a transversal axis. Instead of one guidance groove 36 and one guidance rail 37 per articulating partner, there are now two guidance grooves 36 and two guidance rails 37 per articulating partner. The purpose of this design is to increase the guiding effect of the grooves and rails as well as to increase the contact area between the articulating partners of this articulation surface at maximum rotation. By altering the widths and the placement of the guidance grooves and rails it is possible to further increase the number of guidance grooves and rails (not shown). Furthermore, it is possible to combine the concept of a higher number of guidance grooves and rails with the concept of helical surfaces which has been described in Figs. 9, 10 and 11 (not shown).

Figure 16 shows different views of the top or bottom plate of the intervertebral disc prosthesis equipped with a total of six webs which provide a means of fixating the plate to the adjacent vertebra. Fig. 16a, 16b and 16c show top, trimetric and front views of the plate and webs. Fig. 16d shows a section view as indicated in Fig. 16c. The figures show a total of six webs, three of which are longer and aligned sagittally and three of which are shorter and aligned transversally. In order to facilitate the penetration of the webs into the vertebra, all webs have pointed top and dorsal faces. The longest sagittally aligned web is slightly higher than the other webs which are all equally high.

Figure 17 shows a variation of Fig. 16, the only difference being the longest sagittally aligned web which is now as high as all other webs.

Figure 18 depicts another variation of Fig. 16. The only web with pointed top and dorsal faces is the longest sagittally aligned web. All other webs have planar faces. Furthermore, a triangular groove is incorporated into the longest sagittally aligned web, providing a greater resistance to ventral dislocation of the plate.

Figure 19 depicts another variation of Fig. 16. The transversally oriented webs are no longer aligned on the same line. Furthermore, the pointed top and dorsal faces of the webs have arch-like forms, and the longest sagittally oriented web has a semicircular groove, providing a greater resistance to ventral dislocation of the plate.

Figure 20 depicts another variation of Fig. 16. The lateral, transversally oriented webs are rotated in such a manner that they form an arrow-like shape with their corresponding sagittally oriented webs. The middle, transversally oriented web is replaced by a web with a triangular basic shape. The idea of both modifications is to facilitate the penetration of the webs into the adjacent vertebra upon implantation and to provide a strong fixation thereafter. All webs have pointed top and dorsal faces.

Figure 21 shows a concept of articulating surfaces of two adjacent prosthesis modules. Fig. 21a shows a trimetric view, Fig 21b a top view, and Figs. 21c and 21d show section views as indicated in Fig. 21a. The construction consists of a concave spherical surface 73, a convex spherical surface 72, four circular recesses 70 and four circular prominences 71. The intent is that the spherical surfaces 72 and 73 form an articulation surface, while the four prominences 71 lie in the corresponding four recesses 70 which are slightly larger than the prominences.. This construction of articulating surfaces allows a limited, coupled rotation of the corresponding prosthesis modules around all three spatial axes

Figure 22 shows a variation of the concept described in Fig. 21. The circular basic shape of the recesses and prominences is replaced by a quadrilateral basic shape. This does still allow limited, coupled rotation around all three spatial axes. However, the rotation is constrained in a less uniform manner, giving more constructional possibilities. To a certain degree, the rotations around the three spatial axes can be constrained differently.

Claims

1. Intervertebral disc prosthesis for the total replacement of the intervertebral disc within the cervical and lumbar spine, comprising an upper module adapted to firmly assemble with an upper vertebral body, a lower module adapted to firmly assemble with a lower vertebral body, and four middle modules located between the upper and lower module, wherein adjacent modules articulate with each other by their facing surfaces, which define an articulation surface, and
    a. wherein an articulation surface comprises at least one protuberance on one module corresponding with at least one recess on the adjacent module for articulation with the protuberance, and each protuberance and recess being surrounded by an edge, and
    b. wherein the corresponding protuberance and recess are constructed in such a manner that two adjacent modules can only rotate around either a sagittal, or a frontal, or a transversal axis, and
    c. wherein the maximal degree of rotation permitted by a single articulation surface is limited by the height and shape of its protuberance and corresponding recess and their respective edges, and
    d. wherein at maximal rotation in each direction of the three axes, the surrounding edges of the corresponding modules have a two-dimensional surface contact.
2. Intervertebral disc prosthesis according to claim 1, wherein the rotation along one axis is limited or defined by at least one articulation surface.
3. Intervertebral disc prosthesis according to any of claim 1 or 2, wherein the three rotation axes are angled with 90 degrees to each other or at least one rotation axis has a different angle to at least one of the other rotation axes.

4. Intervertebral disc prosthesis according to any of the claims 1 to 3, wherein at least two rotation axes have no intersection point.

5. Intervertebral disc prosthesis according to any of the claims 1 to 4, wherein the protuberance and corresponding recess of at least one articulation surface of two adjacent modules are completely surrounded by an edge.

6. Intervertebral disc prosthesis according to any of the claims 1 to 5, wherein at least two modules are exchangeable by a single module or a single module is exchangeable by at least two modules.

7. Intervertebral disc prosthesis according to any of the claims 1 to 6, wherein middle modules are removable.

8. Intervertebral disc prosthesis according to any of the claims 1 to 7, wherein at least two adjacent modules are firmly, but reversible assembled to each other, either allowing or preventing a rotation around the respective axis.

9. Intervertebral disc prosthesis according to any of the claims 1 to 8, wherein at least two adjacent modules are firmly assembled two each other without any rotation around the respective axis.

10. Intervertebral disc prosthesis according to any of claims 1 to 9, wherein all articulation surfaces determine mono-directional, bi-directional or three-directional motion or a coupled motion thereof around the sagittal, frontal and/or transversal axis.

11. Intervertebral disc prosthesis according to any of the claims 1 to 10, wherein only rotation around two axes is possible, preferably around the sagittal and transversal axes.

12. Intervertebral disc prosthesis according to any of the claims 1 to 11, wherein each module is constructed in one piece or firmly, but reversibly assembled of at least two pieces.

13. Intervertebral disc prosthesis according to any of the claims 1 to 12, wherein protuberance and recess have a spherical, cylindrical, torus-like and/or cone-like shape or a combination thereof and protuberances and corresponding recesses have identical or different radii.

14. Intervertebral disc prosthesis according to any of the claims 1 to 13, wherein the edge of the articulation surface for the axial rotation around the transversal axis comprises

at least two sub-surfaces with alternating gradients for soft limitation of rotation around the transversal axis.

15. Intervertebral disc prosthesis according to any of the claims 1 to 14, wherein the edge of the articulation surface for the rotation around the transversal axis comprises at least two separate helices that are shifted towards each other for soft limitation of rotation around the transversal axis..

16. Intervertebral disc prosthesis according to any of the claims 1 to 15, wherein protuberances and recesses have groove-and-tongue joints for the limitation of the range of motion of adjacent modules against each other.

17. Intervertebral disc prosthesis according to any of the claims 1 to 16, wherein upper and lower module have on their outer sides for assembly with a vertebral body combined sagittally and frontally orientated webs, preferably at least one cross-shaped anchor, optionally in combination with anchoring teeth.

18. Intervertebral disc prosthesis according to any of the claims 1 to 17, wherein the cross-shaped anchor and/or the outer sides of upper and lower module for assembly with a vertebral body are means or have means for an instrument to hold the prosthesis during implantation or explantation.

19. Intervertebral disc prosthesis according to any of the claims 1 to 18, wherein the centre of rotation of the transversal axis is determined by the position and/or shape of protuberance and recess of the articulation surface.

20. Intervertebral disc prosthesis according to any of the claims 1 to 19, wherein upper and lower surface of at least one module

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Claims searched:	1-20	**Date of search:**	15 October 2009

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1-4, 9-13, 19	US 7485146 B1 (CROOK et al) See the summary of the invention in columns 1-4, and the figures
X	1-4, 9-13, 19	WO 2004/002291 A2 (BLAIN et al) See at least page 7, line 24, to page 8, line 9, and the figures
Y	1-4, 10-13, 19	US 2006/122703 A1 (AEBI et al) See the whole document
Y	1-4, 10-13, 19	US 2008/015698 A1 (MARINO et al) See the summary of the invention on pages 1-2, and the figures
Y	1-4, 10-13, 19	US 2006/167552 A1 (KELLER) See the whole document

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X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
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A61F

The following online and other databases have been used in the preparation of this search report

EPODOC, WPI

International Classification:

Subclass	Subgroup	Valid From
A61F	0002/44	01/01/2006