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102016000051280 18 May 2016 (18.05.2016) IT(71) Applicants: **POLITECNICO DI TORINO** [IT/IT]; C.so
Duca degli Abruzzi, 24, 10129 Torino (IT). **ISTITUTO**
ORTOPEDICO RIZZOLI [IT/IT]; Via di Barbiano, 1/10,
40136 Bologna (IT).(72) Inventors: **FERRARESI, Carlo**; c/o POLITECNICO DI
TORINO, C.so Duca degli Abruzzi, 24, 10129 Torino (IT).
FRANCO, Walter; c/o POLITECNICO DI TORINO, C.so
Duca degli Abruzzi, 24, 10129 Torino (IT). **MAFFIODO,**
Daniela; c/o POLITECNICO DI TORINO, C.so Duca degli
Abruzzi, 24, 10129 Torino (IT). **LEARDINI, Alberto**; c/o
ISTITUTO ORTOPEDICO RIZZOLI, Via Barbiano, 1/10,
40136 Bologna (IT).(74) Agent: **LISA, Elisabetta** et al.; PRAXI INTELLECTUAL
PROPERTY S.P.A., Corso Vittorio Emanuele II, 3, 10125
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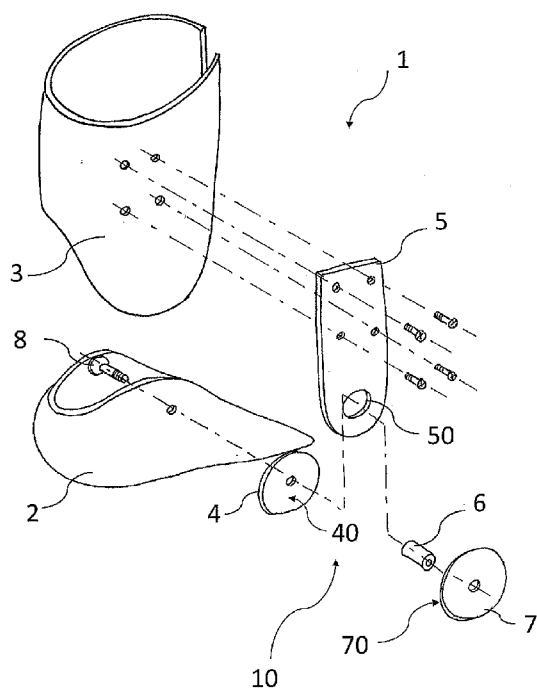


Fig. 2

(57) **Abstract:** The invention relates to an articulated orthosis (1,1') comprising a first shell (2,2') to be associated to a foot (20,20'), a second shell (3,3') to be associated to a leg (30,30'), and a pair of joints (10,10',10'',10'''); each joint (10,10',10'',10''') in turn comprises a first inner plate (4,4',4'',4''') integral with the first shell (2,2') on the opposite side to the foot (20,20'), a second outer plate (5,5',5'',5''') integral with the second shell (3,3') on the opposite side to the leg (30,30') and provided with a hole (50,50',50'',50'''), a spacer (6,6',6'',6'''), a threaded counter-plate (7,7',7'',7'''), and a connecting pin (8,8',8'',8''') integral with the first inner plate (4,4',4'',4''') and whose head is in abutment on the first shell (2,2') on the side opposite to the first inner plate (4,4',4'',4'''), wherein the hole (50,50',50'',50''') of the second outer plate (5,5',5'',5''') has a diameter greater than the diameter of the spacer (6,6',6'',6''') to obtain a mutual radial clearance, and wherein the spacer (6,6',6'',6''') passes through the hole (50,50',50'',50''') of the second outer plate (5,5',5'',5''') and is arranged in contact with the first inner plate (4,4',4'',4''') and with the threaded counter-plate (7,7',7'',7'''), and wherein the distance between the outer surface (40) of the first plate (4,4',4'',4''') and the inner surface (70) of the threaded counter-plate (7,7',7'',7''') is determined by the length of the spacer (6,6',6'',6''') and is greater than the thickness of the second outer plate (5,5',5'',5''') to obtain a mutual axial clearance, so that the pair of said joints (10,10',10'',10''') has the axes of the connecting pins (8,8',8'',8''') aligned with each other and allows the first shell (2,2') and the second shell (3,3') to perform a relative movement with six degrees of freedom consisting in two independent translations in the sagittal plane, a translation in the mediolateral direction, a rotation in the sagittal plane with respect to a mediolateral axis, a rotation in the frontal plane with respect to an



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anterior-posterior axis and a rotation in the transverse plane with respect to a longitudinal axis, so that the axis of rotation of the pair of joints (10,10',10'',10''') is floating around the anatomical center of a user's anatomical joint and the articulated orthosis (1,1') follows the natural kinematics of the user's anatomical joint.

“Articulated ankle-foot orthosis with a floating axis of rotation”**DESCRIPTION****TECHNICAL FIELD**

The present invention relates to the biomedical field and specifically to orthotic devices.

More particularly the present invention relates to ankle-foot orthoses; still more particularly the present invention relates to articulated ankle-foot orthoses usually employed in orthopedic-rehabilitation fields.

The articulated orthosis according to the present invention has a preferred and advantageous application for ankle-foot, but it can also be applied to a knee or elbow and, generally, for treating and healing injuries to musculoskeletal or neurological system.

PRIOR ART

An orthosis is an externally applied device used to support, align, prevent or correct functionalities of movable parts of the body; particularly ankle-foot orthoses (AFO) are applied to tibiotarsal joints (between the leg composed of bone segments of tibia and fibula, and the tarsus, namely the hind foot, particularly talus bone) and subtalar joint (between talus bone and calcaneus), acting contemporaneously for supporting and correcting possibly impaired functions and for constraining the motion in order to protect injured anatomical structures in post-traumatic treatments (see references [1], [2] and [3]).

Among the several types of ankle-foot orthoses those called as articulated orthoses are known, namely “Hinged AFO (HAFO)”, that is ankle-foot orthoses that provide two rigid shells, for foot and leg of a user, connected by joints that allow them to accomplish a relative motion, particularly flexion-extension motions (dorsiflexion and plantar flexion of the foot), within a given range delimited by suitable stop elements, while they oppose, in a more or less strong manner, the motions in other planes; articulated ankle-foot orthoses can have many applications, as in the case of users suffering from foot drop, clubfoot, hemiplegia and other diseases of the lower

limb.

Joints connecting the shells in current articulated orthoses are usually of the fixed-axis rotary type or, more generally, are kinematic chains that allow a limited number of relative degrees of freedom to be performed; therefore a common feature of said articulated ankle-foot orthoses known up to now is the fact of having an axis of rotation that disregard physiological conditions of kinematics of the ankle joint (see reference [3]), that on the contrary moves from one to another position (see references [3], [4], [5], [6] and [7]); a scientific publication about the study of the articular kinematics of the ankle, particularly a method for determining, by motion analysis, the behavior of the natural anatomical joint axis (see reference [8]), discloses that the ankle works as a joint with a single degree of freedom, whose axis of rotation rotates and moves when performing the articular motion, based on the coupling between bone segments and on the action of the ligaments; another recent study (see reference [3]) performed by the motion analysis on such type of orthoses with configurable axis of rotation, has shown that the position of the joint in a conventional articulated orthosis considerably affects the angular motion of the subtalar joints and the overall walking since it does not allow a physiological walking condition to be obtained.

That is to say, the natural movement of the ankle, here defined as relative motion between leg and foot considered as rigid segments, can be taken as a helical movement whose axis is not fixed but changes in position and orientation with respect to such rigid segments; this involves that the constraint exerted by the conventional orthosis to the user anatomical joint causes unnatural movement that can lead to, in continuative use, undesired and harmful effects both for the structures of the involved anatomical joint and for the adjacent anatomical joints.

Currently the most used models of articulated orthoses are generally classified as it follows:

- with simple hinge, with or without limitation of the range of motion (ROM), with or without elastic resistance proportional to the rotation; with bar joints, that is with two joints, arranged in a medial and lateral position, each one composed of a rigid

bar hinged at the ends by two shells that provide two degrees of freedom in the sagittal plane:

- "Tamarack", namely with the two shells connected by flexible elements in medial and lateral position, allowing a relative motion to be performed with greater freedom with respect to the hinge;
- with polycentric joint, where the relative motion between the two shells follows a predetermined trajectory.

Particularly the articulated ankle-foot orthoses described in the international application published under n. WO2014/060824 A1 and in US patents n. US5,086,760 and US 5,094,232 are known.

The international application published under n. WO2014/060824 A1 discloses an articulated ankle-foot orthosis comprising joint, leg shell and foot shell, wherein the joint allows a roto-translation motion with only one degree of freedom between the leg shell and the foot shell; particularly such roto-translation motion depends on the geometry of the joint that, by means of two mobile pins in two corresponding recesses, constrains and defines the trajectory of such motion.

Said technical solution, while dealing with the problem of allowing a natural movement when walking, particularly allowing the foot to perform flexion-extension natural movements according to a roto-translation motion, is limited as regards the functionality perspective since it allows only one degree of freedom to be performed between the shells; particularly such solution changes the natural articular kinematics of the ankle, that cannot be represented as a rotation about a fixed axis.

The US patent n. US 5,086,760 on the contrary is about a joint allowing the flexion-extension motion to be performed by the rotation about the axis of a pin; the joints, by means of two spherical surfaces, allows also the inversion-eversion motion to be performed, where the two axes of rotation are forced to pass by a fixed point at the center of the spherical surfaces; therefore it is a joint with two degrees of freedom, having the possibility of regulating the limit stop elements for the two rotations.

Said technical solution has the drawbacks of allowing only two degrees of freedom of rotation about axes forced to pass by a fixed point; particularly such solution alters

the natural articular kinematics of the ankle, that cannot be represented as a motion with two degrees of freedom.

The US patent n. US 5,094,232 relates to a joint allowing three degrees of freedom on the sagittal plane, by the provision of two flat plates, each one provided with a groove and arranged at 90° with respect to each other; the two plates, always in contact with each other, are coupled by a sphere, such to allow movements of horizontal translation, vertical translation and rotation in the sagittal plane to be performed.

Said technical solution has the drawbacks of allowing only three degrees of freedom in the sagittal plane of the orthosis, possibly obtaining two further degrees of freedom (relative rotations in the frontal plane and transverse plane) by acting on the deformability of the attachments to the leg shell and not by means of the joint itself; particularly such solution alters the natural articular kinematics of the ankle, that requires six relative degrees of freedom between the segments of the leg and foot.

Therefore all the solutions known up to now, among which the one mentioned above, do not allow six degrees of freedom of relative movement to be performed, that is to say three degrees of freedom in the sagittal plane (flexion-extension rotation, horizontal translation and vertical translation), a fourth degree of freedom in the frontal plane (inversion-eversion rotation), a fifth degree of freedom in the transverse plane (abduction-adduction rotation) and a sixth degree of freedom in the mediolateral direction (translation).

Accordingly none of the known solutions provides an articulated orthosis able not to alter the natural movement of ankle-foot anatomical joint.

Moreover none of the known solutions provides an articulated orthosis such that the relative motion between the two shells is guided by the structures of the natural anatomical joint and contemporaneously provided with constraining elements able to compensate for possible weaknesses, or necessary functional protections, of natural containment structures.

Moreover none of the known solutions provide to design and make an articulated orthosis based on the physiological features of the single user by adapting a two shell

joint produced according to industrial standards and methods in a customized manner, namely none of the known solutions can fit specific needs of each individual user.

In the current scenario, in spite of the considerable technological development and the plurality of available articulated orthoses, it is however difficult to combine the greatest efficacy as regards therapeutic-rehabilitation aspect with an increased comfort of use, and a more important problem is that it is often necessary to purchase different orthoses for the various therapeutic-rehabilitation phases of a user.

Therefore there is the unsatisfied need for an articulated orthosis, and more precisely for a corresponding joint, able to provide six degrees of freedom in the movement, namely three degrees of freedom in the sagittal plane (rotation, horizontal translation and vertical translation), a fourth degree of freedom in the frontal plane (rotation), a fifth degree of freedom in the transverse plane (rotation) and a sixth degree of freedom in the mediolateral direction (translation).

Moreover there is the unsatisfied need for an articulated orthosis, and more precisely for a corresponding joint, able to guarantee a relative movement between the two shells complying with the physiological constraints of the anatomical joint.

Moreover there is the unsatisfied need for an orthosis wherein the relative movement between the two shells is guided by the structures of the anatomical joint and that, at the same time, is provided with constraining elements able to compensate for possible weaknesses, or necessary functional protections, of natural containment structures.

Moreover there is the unsatisfied need for a single articulated orthosis and more precisely a corresponding relevant joint, that can fit different users and, with reference to a single user, that can fit the different therapeutic-rehabilitation phases.

Moreover there is the unsatisfied need of reducing manufacturing costs, particularly for mass productions.

OBJECTS AND SUMMARY OF THE INVENTION

It is the object of the present invention to overcome prior art drawbacks of the field of orthotic devices, specifically articulated orthoses.

More precisely the present invention intends to solve the problem of providing an articulated orthosis wherein the joint connecting the two shells allows a relative movement with six degrees of freedom appropriately limited, such to guarantee a physiological behavior of the user anatomical joint, and at the same time to compensate for possible weaknesses of natural containment structures or to provide them with the necessary functional protections.

Particularly the object of the present invention is to provide an articulated orthosis equipped with an innovative joint for the connection of the two shells that, unlike a conventional fixed-axis rotary joint that limits the relative motion only to one degree of freedom, allows a more free relative movement to be provided, that is more easily guided by the structures of the anatomical joint even if within a confined space (flexion-extension movements are encouraged, while other movements are limited, namely pronosupination, abduction-adduction and the three articular translations).

Still more particularly the object of the present invention is to provide an articulated orthosis that adapts the relative movement of the shells to the movement of the mobile instantaneous helical axis (IHA) typical of a natural ankle, by providing a joint with a floating axis of rotation for connecting the two shells of the orthosis and by positioning the mean axis of the floating joint at the "ideal" axis of the ankle of the user (such "ideal" axis being taken as corresponding to the mean helical axis (MHA)).

Moreover the object of the present invention is to provide an articulated orthosis that can fit any user and also different therapeutic-rehabilitation phases of a single user, by being designed and made on the basis of the specific kinematic characteristics of the user ankle, obtained by suitable motion analysis tools and protocols.

Said and other objects and advantages of the invention, that will be more clear for the description below, are achieved by an articulated orthosis as the one according to claim 1.

Preferred embodiments and variants of the orthosis of the present invention are the subject matter of the dependent claims; particularly in a preferred and advantageous embodiment, the articulated orthosis according to the invention provides means for adjusting the position of the joint.

In a further preferred and advantageous embodiment the articulated orthosis according to the invention provides first or second elastic deformable elements, transverse or axial ones respectively, to control in a more accurate manner the joint clearances.

- 5 It has to be noted that all the annexed claims are an integral part of the present description and that each one of the technical characteristics claimed therein is possibly independent and usable autonomously from other aspects of the invention. It is immediately clear that it is possible to make many changes to what described (for example as regards shape, dimensions, arrangements and parts with equivalent
- 10 functionalities) without departing from the scope of protection of the invention as claimed in the annexed claims.

Advantageously, the technical solution according to the present invention that provides an articulated orthosis with an instantaneous helical axis (IHA) floating about the mean helical axis (MHA) of the user's ankle makes it possible:

- 15 - to reproduce the natural movement of the user's ankle;
- to provide six relative movements, three movements in the anatomical sagittal plane, one movement in the anatomical frontal plane, one movement in the anatomical transverse plane and one movement in the mediolateral direction;
- to fit any user and to be customized for his/her specific needs and also, for each
- 20 user, for the various phases of the motor rehabilitation treatment;
- a higher efficacy as regards the therapeutic-rehabilitation aspect;
- an optimal comfort of the user combined with a considerable reduction of pain;
- easiness of adjustment;
- high durability, lightweight and low friction;
- 25 - simple and cheap mass production, also by the possibility of using 3D printing technology.

Further advantageous characteristics will be more clear from the following description of some preferred but not exclusive embodiments, provide by way of example and not as a limitation.

30 **BRIEF DESCRIPTION OF THE DRAWINGS**

The invention will be described here below with reference to some preferred embodiments, provided by way of example and not as a limitation, with reference to the annexed drawings. These drawings show different aspects and examples of the present invention and, where appropriate, like structures, components, materials and/or elements in different figures are denoted by like reference numerals.

FIG. 1 is a perspective, partially phantom, view, of the articulated orthosis according to the present invention comprising joint, leg shell (top) and foot shell (bottom);

FIG.2 is an exploded perspective view of FIG.1;

FIG. 3 is a side view (top) and a plan view (bottom) of FIG.1;

FIG. 4A is a side view (top) and a plan view (bottom) of the leg shell of FIG.3 with the joint parts integral therewith;

FIG. 4B is a side view (top) and a plan view (bottom) of the foot shell of FIG.3 with the joint parts integral therewith;

FIG. 5A is a first relative rotation movement in the sagittal plane, in the system of FIG.3;

FIG. 5B is a second relative horizontal translation movement in the sagittal plane, in the system of FIG.3;

FIG. 5C is a third relative vertical translation movement in the sagittal plane, in the system of FIG.3;

FIG. 5D is a fourth relative rotation movement in the frontal plane, in the system of FIG.3;

FIG. 5E is a fifth relative rotation movement in the transverse plane, in the system of FIG.3;

FIG. 5F is a sixth relative translation movement in mediolateral direction, in the system of FIG.3;

FIG. 6 is a cross-section view of the joint of FIG.1;

FIG.7 is a perspective, partially phantom, view of a first alternative embodiment, with joint positioning plates, of the articulated orthosis according to the present invention;

FIG. 8 is an exploded perspective view of FIG. 7;

FIG. 9A is a cross-section view of a first variant of the joint, provided with viscoelastic elements deformable in the axial direction, of the articulated orthosis according to the present invention; and

FIG. 9B is a cross-section view of a second variant of the joint, provided with viscoelastic elements deformable in the radial direction, of the articulated orthosis according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

While the invention is susceptible of various modifications and alternative constructions, some preferred embodiments are shown in the drawings and will be described in details herein below.

It should be understood, however, that there is no intention to limit the invention to the specific disclosed embodiments but, on the contrary, the invention intends to cover all the modifications, alternative constructions and equivalents that fall within the scope of the invention as defined in the claims.

Therefore in the description below the use of “for example”, “etc.”, “or” denotes non-exclusive alternatives without limitation, unless otherwise noted; the use of “also” means “also, but not limited to”, unless otherwise noted; the use of “includes/comprises” means “includes/comprises, but not limited to”, unless otherwise noted.

The articulated orthosis of the present invention is based on the consideration that the natural motion of the ankle can be interpreted as a motion according to a mobile instantaneous helical axis (Instantaneous Helical Axis - IHA), floating about a mean helical axis (Mean Helical Axis - MHA); the bundle of the instantaneous axes IHA and the corresponding mean axis MHA of the user intended to receive the orthosis can be determined by known motion analysis tools and protocols for example by stereophotogrammetry, use of inertial sensors, fluoroscopy.

The main characteristic of said articulated orthosis is the fact of providing a floating joint for connecting the two shells to the orthosis, that adapts the relative movement of the shells to the movement of the bundle of the instantaneous helical axes IHA of the user's ankle, and the fact of positioning the mean axis of the joint coinciding with

the mean helical axis MHA of the user's ankle.

As mentioned above, it is possible to perform the kinematic analysis of the relative motion between two rigid bodies, namely particularly the two shells of the articulated orthosis, by identifying IHA and MHA by known calculation methods and procedures. Such methods can be applied also for kinematically identifying *in vitro* human anatomical joints, as described in a preceding study (see reference [8]).

The application *in vivo* of such methods, that is possibly on the user intended to receive the orthosis, on the contrary leads to important problems, particularly determined by the multi-segment aspect of the foot and by the presence of soft tissues, that generate a spurious movement between markers, necessarily skin markers, and the underlying bone segments, that are the targets of the measurements. For example think of using stereophotogrammetry, such markers have to be applied to the user, whose spatial coordinates are detected for different movements, such as walking, free or forced flexion-extension of the ankle, both active and passive one, etc., and are processed by mathematical algorithms that allow instantaneous helical axes IHA and the mean helical axis MHA to be calculated and graphically represented in a three-dimensional space. It has to be pointed out that in order to apply such method, it is necessary to identify a rigid body model of the foot, operation affected by high numerical noise that generates high scattering values of the results; therefore in order to obtain an efficacious kinematic identification of the ankle it will be necessary to apply also techniques filtering and optimizing the calculated values.

The mean axis MHA of the bundle of instantaneous axes IHA, calculated in this manner, then allows the mean axis of the joint connecting the two shells to be defined.

On the basis of what mentioned above, the articulated orthosis of the present invention is provided with an innovative joint for connecting the two shells that, unlike conventional fixed-axis rotary joints that limit the relative motion only to one degree of freedom, or unlike other solutions allowing some further degrees of freedom, it allows a completely free relative movement to be performed, that is thus

more easily guided by the structures of the natural anatomical joint even if within a confined space (the flexion-extension movement is encouraged, while the other movements are limited, that is pronosupination, abduction-adduction, and the three articular translations); thus when walking the orthosis allows the natural articular movement to be performed defined by the passive articular structures (capsule, cartilaginous surfaces and ligaments) between bone segments, however exerting a constraint action as regards the movements that in not injured anatomical joint usually are limited by the containment physiological structures just mentioned above.

10 With reference to Figs. 1 and 2 they show the articulated orthosis 1 according to the present invention that comprises:

- a first shell 2 to be associated to a foot 20,
- a second shell 3 to be associated to a leg 30, and
- a pair of joints 10.

15 Preferably the first shell 2 and the second shell 3 are made of a thermoplastic material and are padded with polyurethane foam; preferably the first shell 2 to be associated to the foot 20 is equipped with anti-slip sole, for example made of rubber; preferably the second shell 3 to the associated to the leg 30 is equipped with closure means, for example one or more hook and loop fastener straps; preferably the regions of the shells near the joint are reinforced with riveted metal plates.

The joint 10 in turn comprises

- a first inner plate 4 integral with the first shell 2 on the opposite side to the foot 20,
- a second outer plate 5 integral with the second shell 3 on the opposite side to the leg 30 and provided with a hole 50,
- a spacer 6,
- a threaded counter-plate 7 and
- a connecting pin 8 integral with said first inner plate 4 and whose head is in abutment on said first shell 2 on the side opposite to said first inner plate 4.

30 In the present description the term "inner plate" means the plate connected to the

foot shell, while the term “outer plate” means the plate connected to the leg shell.

The hole 50 of the second outer plate 5 has a diameter greater than the diameter of the spacer 6 to obtain a mutual radial clearance.

Moreover the distance between the outer surface 40 of the first inner plate 4 and the
5 inner surface 70 of the threaded counter-plate 7, determined by the length of the spacer 6, is greater than the thickness of the second outer plate 5 to obtain a mutual axial clearance.

As clearly visible in Figs. 2 and 6, the first inner plate 4 is connected with the first
shell 2 on the side opposite to the foot 20, the second outer plate 5 is connected with
10 the second shell 3 on the side opposite to the leg 30, the spacer 6 passes through the hole 5 of the second outer plate 5 and is arranged in contact with the first inner plate 4 and the threaded counter-plate 7 is arranged in contact with the spacer 6.

Thus the axis of rotation of the pair of joints 10 is floating around the MHA of a
user’s anatomical joint so that the articulated orthosis 1 follows the natural
15 kinematics of the user’s anatomical joint.

Particularly a pair of joints 10 allows the first shell 2 and the second shell 3 to
accomplish a relative movement with six degrees of freedom consisting in two
independent translations in the sagittal plane (as visible in Figs. 5B and 5C
respectively), a translation in the mediolateral direction (as visible in Fig. 5F), a
20 rotation in the sagittal plane with respect to a mediolateral axis (as visible in Fig. 5A),
a rotation in the frontal plane with respect to an anterior-posterior axis (as visible in
Fig. 5D) and a rotation in the transverse plane with respect to a longitudinal axis of
the leg (as visible in Fig. 5E).

Figs. 3, 4A and 4B show the articulated orthosis 1 to comprise a pair of joints 10; the
25 connection between the two shells 2 and 3 is performed by a pair of joints 10 that
allow relative movements with a specific amplitude, particularly as regards the
rotation and the two translations in the sagittal plane, the translation in the
mediolateral direction, the rotation in the frontal plane with respect to an anterior-
posterior axis and the rotation in the transverse plane with respect to a longitudinal
30 axis.

The difference between the outer diameter of the spacer 6 and the diameter of the holes 50 of the second outer plate 5 allows three degrees of freedom in the sagittal plane to be accomplished; the difference between the thickness of the second outer plate 5 and the distance between the outer surface 40 of the first inner plate 4 and the inner surface 70 of the threaded counter-plate 7, set by the length of the spacer 6, allows the further translation movements in the mediolateral direction and rotation movement in the frontal plane and in the transverse plane to be accomplished.

Thus the six degrees of freedom obtained in this manner allow a physiological movement of the axis of rotation of the ankle, that can move in space and change its inclination. Thus the orthosis does not alter the natural movements of the anatomical joint, but it limits them within specific amplitudes.

The amplitudes allowed to the different natural movements, except for the flexion-extension movement, can be determined and modified by simply defining the values of the length and outer diameter of the spacer 6 that will be fitted in each joint 10.

Thus it will be possible for example to allow only the flexion-extension movement about the natural MHA of the user, by fitting in each joint 10 a spacer 6 with an outer diameter equal to the diameter of the hole 50 and with a length equal to the thickness of the second outer plate 5; or the therapist will have the possibility of deciding the amplitude of the inversion-eversion movements and abduction-adduction movements by simply inserting in each joint 10 a spacer 6 with a specific outer diameter and length.

In a possible industrial application of the orthosis it will be possible to easily define the values of the dimensional differences between the parts of the joint 10 coupled in relative motion, namely the outer diameter of the spacer 6 with respect to the diameter of the hole 50, as well as the length of the spacer 6 with respect to the thickness of the plate 5, once the values of the amplitudes of the desired natural movements are established.

Preferably the first inner plate 4, the second outer plate 5 and the threaded counter-plate 7 are made of or are covered by a low friction material.

With reference to Figs. 7 and 8 they show a first alternative embodiment of the

articulated orthosis 1' according to the present invention.

Besides the essential constructional elements (a first shell 2' to be associated to a foot 20'; a second shell 3' to be associated to a leg 30'; a pair of joints 10' each comprising, in turn, a first inner plate 4', a second outer plate 5' provided with a hole 50', a spacer 6', a threaded counter-plate 7' and a connecting pin 8' integral with said first inner plate 4', which are likewise those shown above with reference to the general embodiment of the invention and that therefore, for brevity reasons, will not be again described in detail) the joint 10' of the articulated orthosis 1' further comprises a third plate 9' arranged between the second shell 3' and the second outer plate 5', to adjust the positioning of the hole 50' with respect to the second shell 3', by a horizontal and a vertical translation in the sagittal plane.

Particularly the third plate 9' has a rectangular shape and is provided with a recess 90', rectangular too, allowing the plate 9' to be fastened in different positions with respect to the shell 3' by means of a pair of screws 91'; it is clear that also other shapes of the third plate 9' and of the recess 90' can be selected that are fit for purpose. Moreover the outer plate 5' has a recess 51' allowing the plate 5' to be fastened in different positions with respect to the plate 9' by means of a pair of screws 52'; it is clear that it is possible to select different shapes of the plate 5' and of the recess 51' that are fit for purpose.

Moreover the joint 10' of the articulated orthosis 1' comprises, in turn, a fourth plate 14', such to allow the position of the connecting pin 8' to be adjusted with respect to the first shell 2', by a horizontal and a vertical translation in the sagittal plane. The fourth plate 14' has a rectangular shape and it is also provided with two recesses 141' and 142' wherein the pin 8' and a further pair of adjustment screws 143' can move respectively.

With reference to Fig. 9A it shows a first variant of the joint 10'' of the articulated orthosis according to the present invention.

The joint 10'' further comprises first viscoelastic transverse elements 11'' arranged between the first inner plate 4'' and the second outer plate 5'' and/or between the second outer plate 5'' and the threaded counter-plate 7'', to control in a way

determined with precision, through stiffness and damping characteristics of the material composing the first viscoelastic elements, the mobility of the joint 10'' allowed in the axial direction by the mutual axial clearance between the first inner plate 4'' and the second plate 5'' and/or the second plate 5'' and the threaded counter-plate 7''.

With reference to Fig. 9B it shows a second variant of the joint 10''' of the articulated orthosis according to the present invention.

The joint 10''' further comprises, in addition or as an alternative to the first viscoelastic transverse elements 11', second axial viscoelastic elements 13'', arranged between the spacer 6''' and the second outer plate 5'', to control in a way determined with precision, through stiffness and damping characteristics of the material composing the second viscoelastic elements, the mobility of the joint 10''' allowed in the sagittal plane by the mutual radial clearance between the hole 50''' of the second outer plate 5''' and the spacer 6'''. The first 11'' and second 13''' viscoelastic elements are provided in such an amount and quality to adjust as desired the mutual clearance of the elements between which they are placed; for example the first 11'' and second 13''' elastic elements can be spring lock washers, Belleville springs, elastomers and the like having specific stiffness values.

The articulated orthosis 1, 1' according to the present invention in any of its embodiments and variants disclosed above, has the diameter of the spacer 6,6',6'',6''' smaller than the diameter of the hole 50,50',50'',50''' of the second outer plate 5,5',5'',5'''; the difference between the diameter of the spacer 6,6',6'',6''' and the diameter of the hole 50,50',50'',50''' of the second outer plate 5,5',5'',5''' determines the amplitude of the relative translation movements in the sagittal plane.

The articulated orthosis 1,1' according to the present invention, in any of the embodiments and variants described above, has a length of the spacer 6,6',6'',6''' greater than the thickness of the second outer plate 5,5',5'',5''', such that the difference determines the amplitude of the relative angular movements in the frontal plane and transverse plane and of the relative translation movement in the mediolateral direction.

The articulated orthosis with floating axis of rotation according to the present invention, here shown in the preferred and advantageous embodiment for ankle-foot can be also applied to a knee or an elbow; generally the articulated orthosis with floating axis of rotation according to the present invention has many fields of application, that result directly from the innovative characteristics and from the advantages described above, for treating and healing ankle-foot injuries to the musculoskeletal or neurological system such as for example the post-traumatic treatment of ligament injuries, chronic ankle instability, post-operative or conservative joint support, foot drop due to neuromuscular deficit associated with paralysis, muscular dystrophy, myelomeningocele or due to other neurological central or peripheral diseases, central or peripheral paralyses with clubfoot, etc or anyway for any need of adjustable dynamic support.

As it results from what disclosed above, the innovative technical solution described herein has the following advantageous characteristics:

- by making a floating joint that matches the orthosis movement to the natural movement of the ankle together with the positioning of the axis of rotation of the orthosis coinciding with the ideal axis of the ankle, unique possibility with respect to current prior art, it reproduces the natural movement of the user's ankle, guaranteeing a behavior as much physiological as possible, in compliance with constraints and restrictions in the articular movement for which the orthosis is used;
- possibility, unique with respect to current prior art, of providing six degrees of freedom of relative movements between the two shells, three movements in the anatomical sagittal plane, one movement in the anatomical frontal plane, one movement in the anatomical transverse plane and one movement in the mediolateral direction;
- due to the fact of making a modular joint using always the same base elements and optionally additional elements, all standardized ones, the possibility of fitting any user and of being customized according to his/her specific needs and also, for each user, according to the various phases of the motor rehabilitation and protection treatment;

- obtaining a higher efficacy as regards the therapeutic-rehabilitation aspect;
- an optimal comfort of the user combined with a considerable reduction of pain;
- easiness of adjustment;
- high durability, lightweight and low friction; and

5 - simple and cheap mass production, also by the possibility of using 3D printing technology.

From the description disclosed above it is therefore clear how the articulated orthosis and the methods described allow the above objects to be achieved.

It is also clear, for a person skilled in the art, that it is possible to make changes and
 10 variants to the solution described with reference to the annexed figures, without for this reason departing from the teaching of the present invention and from the scope of protection as defined in the annexed claims.

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CLAIMS

1. An articulated orthosis (1,1') comprising

- a first shell (2,2') to be associated to a foot (20,20'),
- a second shell (3,3') to be associated to a leg (30,30'), and
- 5 - a pair of joints (10,10',10'',10''')

characterized in that each joint (10,10',10'',10''') comprises

- a first inner plate (4,4',4'',4''') integral with said first shell (2,2') on the opposite side to said foot (20,20'),
- a second outer plate (5,5',5'',5''') integral with said second shell (3,3') on the
- 10 opposite side to said leg (30,30') and provided with a hole (50,50',50'',50'''),
- a spacer (6,6',6'',6'''),
- a threaded counter-plate (7,7',7'',7'''), and
- a connecting pin (8,8',8'',8''') integral with said first inner plate (4,4',4'',4''') and whose head is in abutment on said first shell (2,2') on the side opposite to
- 15 said first inner plate (4,4',4'',4'''),

wherein said hole (50,50',50'',50''') of said second outer plate (5,5',5'',5''') has a diameter greater than the diameter of said spacer (6,6',6'',6''') to obtain a mutual radial clearance,

and wherein said spacer (6,6',6'',6''') passes through said hole (50,50',50'',50''') of

20 said second outer plate (5,5',5'',5''') and is arranged in contact with said first inner plate (4,4',4'',4''') and with said threaded counter-plate (7,7',7'',7'''),

and wherein the distance between the outer surface (40) of said first inner plate (4,4',4'',4''') and the inner surface (70) of said threaded counter-plate (7,7',7'',7''') is determined by the length of said spacer (6,6',6'',6''') and is greater than the

25 thickness of said second outer plate (5,5',5'',5''') to obtain a mutual axial clearance,

so that said pair of joints (10,10',10'',10''') has the axes of said connecting pins (8,8',8'',8''') aligned with each other and allows said first shell (2,2') and said second shell (3,3') to perform a relative movement with six degrees of freedom

30 consisting in two independent translations in the sagittal plane, a translation in

the mediolateral direction, a rotation in the sagittal plane with respect to a mediolateral axis, a rotation in the frontal plane with respect to an anterior-posterior axis and a rotation in the transverse plane with respect to a longitudinal axis,

5 so that the axis of rotation of said pair of joints (10,10',10'',10''') is floating around the anatomical center of a user's anatomical joint and said articulated orthosis (1,1') follows the natural kinematics of said user's anatomical joint.

2. An articulated orthosis (1') according to claim 1, wherein said joint (10') further comprises a third plate (9'), arranged between said second shell (3') and said
10 second outer plate (5'), to adjust the positioning of said hole (50,50',50'',50''') with respect to said second shell (3'), by means of a horizontal translation and of a vertical translation in the sagittal plane.

3. An articulated orthosis (1') according to claim 1 or 2, wherein said joint (10') further comprises a fourth plate (14'), arranged between said first shell (2') and
15 said second outer plate (5'), to adjust the positioning of said connecting pin (8') with respect to said first shell (2'), by means of a horizontal translation and of a vertical translation in the sagittal plane.

4. An articulated orthosis (1,1') according to any of the preceding claims, wherein said spacer (6,6) inserted in each of said joints (10,10') has a length and an outer
20 diameter such as to reduce or completely restrain the movements of abduction-adduction and of inversion-eversion allowed to the two shells by said pair of joints (10,10').

5. An articulated orthosis (1,1') according to any of the preceding claims, wherein said joint (10'') further comprises first viscoelastic elements (11''), arranged
25 between said first inner plate (4'') and said second outer plate (5'') and/or between said second outer plate (5'') and said threaded counter-plate (7''), to control in a way determined with precision, through the stiffness and damping properties of the material forming said first viscoelastic elements (11''), the mobility of said joint (10'') allowed in the axial direction by said mutual axial
30 clearance between said first inner plate (4'') and said second outer plate (5'')

and/or said second outer plate (5'') and said threaded counter-plate (7'').

6. An articulated orthosis (1,1') according to any of the preceding claims, wherein said joint (10''') further comprises second viscoelastic elements (13'''), arranged between said spacer (6''') and said second outer plate (5'''), to control in a way
 5 determined with precision, through the stiffness and damping properties of the material forming said second viscoelastic elements (13'''), the mobility of said joint (10''') allowed in the sagittal plane by said mutual radial clearance between said hole (50,50',50'',50''') of said second outer plate (5,5',5'',5''') and said spacer (6,6',6'',6''').
- 10 7. An articulated orthosis (1,1') according to any of the preceding claims, wherein said first viscoelastic elements (11'') and said second viscoelastic elements (13''') are spring lock washers, Belleville springs, elastomers and the like having defined stiffness values.
- 15 8. An articulated orthosis (1,1') according to any of the preceding claims, wherein said hole (50,50',50'',50''') has an elliptical shape and has a radial clearance with respect to said spacer (6,6',6'',6'''), so that, in the sagittal plane, the mutual translation between said second outer plate (5,5',5'',5''') and said first inner plate (4,4',4'',4''') has different amplitudes in different directions.
- 20 9. An articulated orthosis (1,1') according to any of the preceding claims, wherein said connecting pin (8,8',8'',8''') has a greater diameter thread at the end onto which said first inner plate (4,4',4'',4''') is screwed near the head of said connecting pin (8,8',8'',8''') and a lower diameter thread at the end onto which said threaded counter-plate (7,7',7'',7''') is screwed opposite to the head of said connecting pin (8,8',8'',8'''), so as to force a definite distance between the outer
 25 surface (40) of said first inner plate (4,4',4'',4''') and the inner surface (70) of said threaded counter-plate (7,7',7'',7'''), thus accomplishing both the proper function of pin (8,8',8'',8''') and that of spacer (6,6',6'',6''').
- 30 10. An articulated orthosis (1,1') according to any of the preceding claims, wherein said first shell (2,2') and said second shell (3,3') are made of thermoplastic material, are padded with polyurethane foam and are reinforced in the areas near

the joints, and wherein said first shell (2,2') is equipped with non-slip sole and wherein said second shell (3,3') is equipped with closure means.

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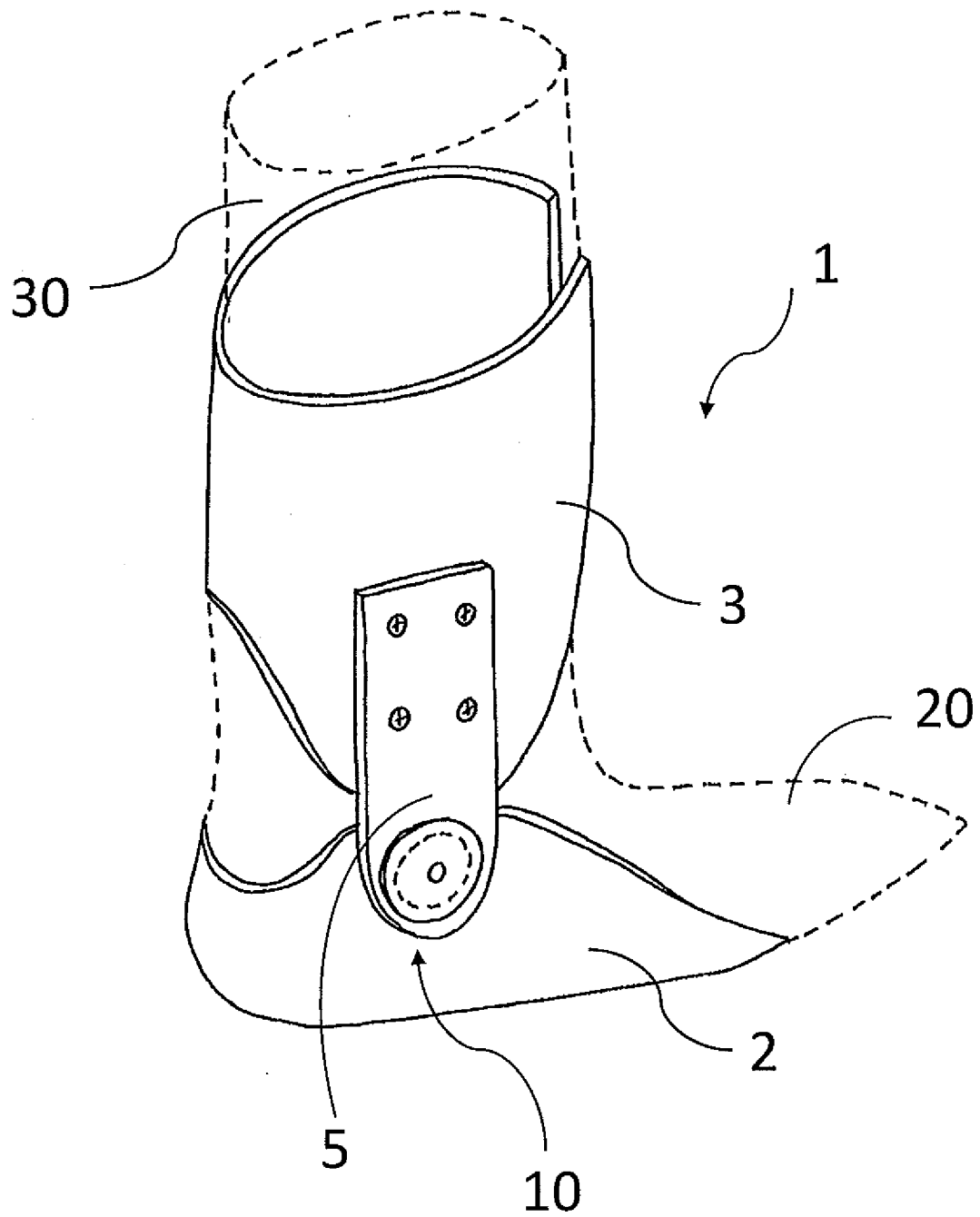


Fig. 1

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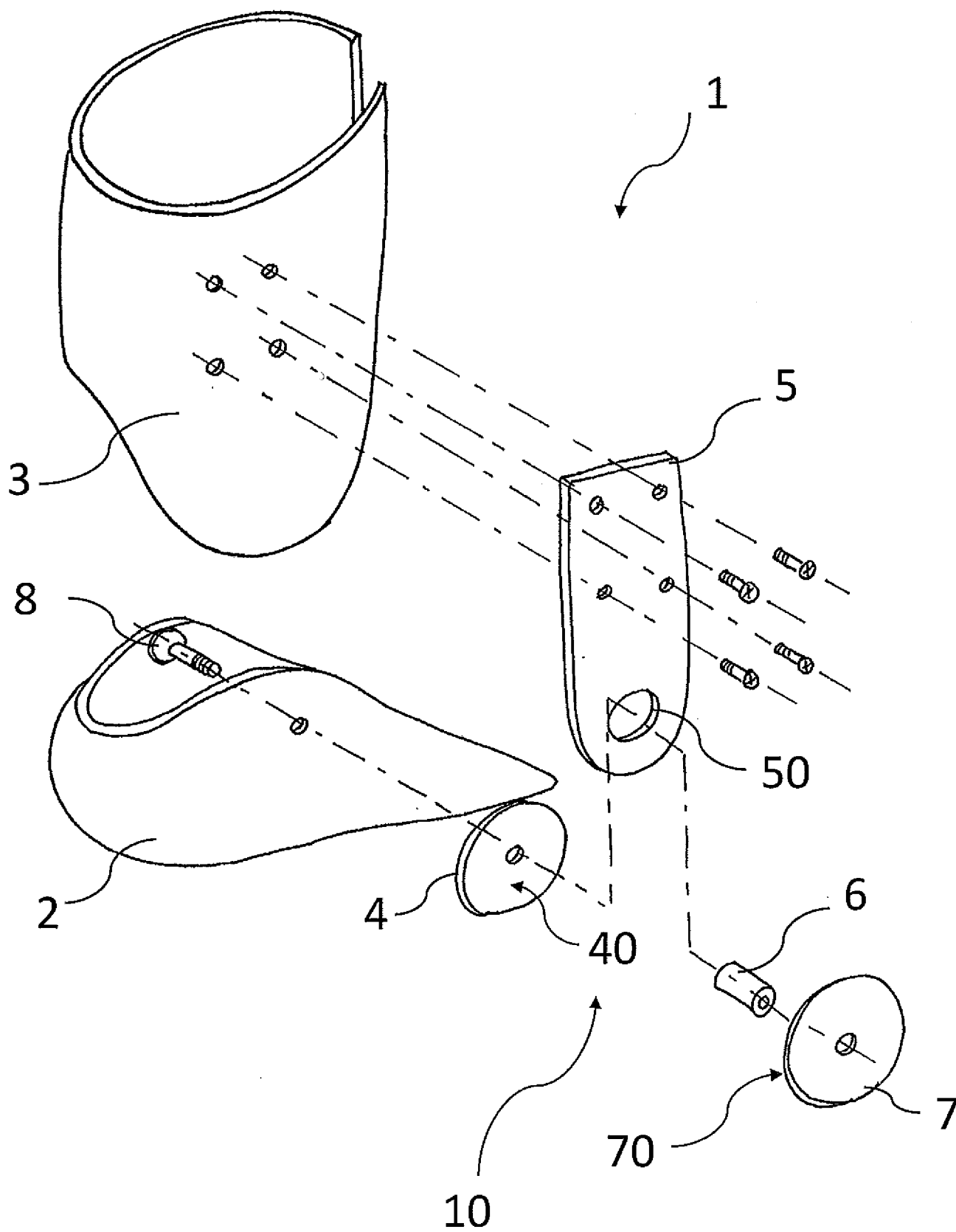


Fig. 2

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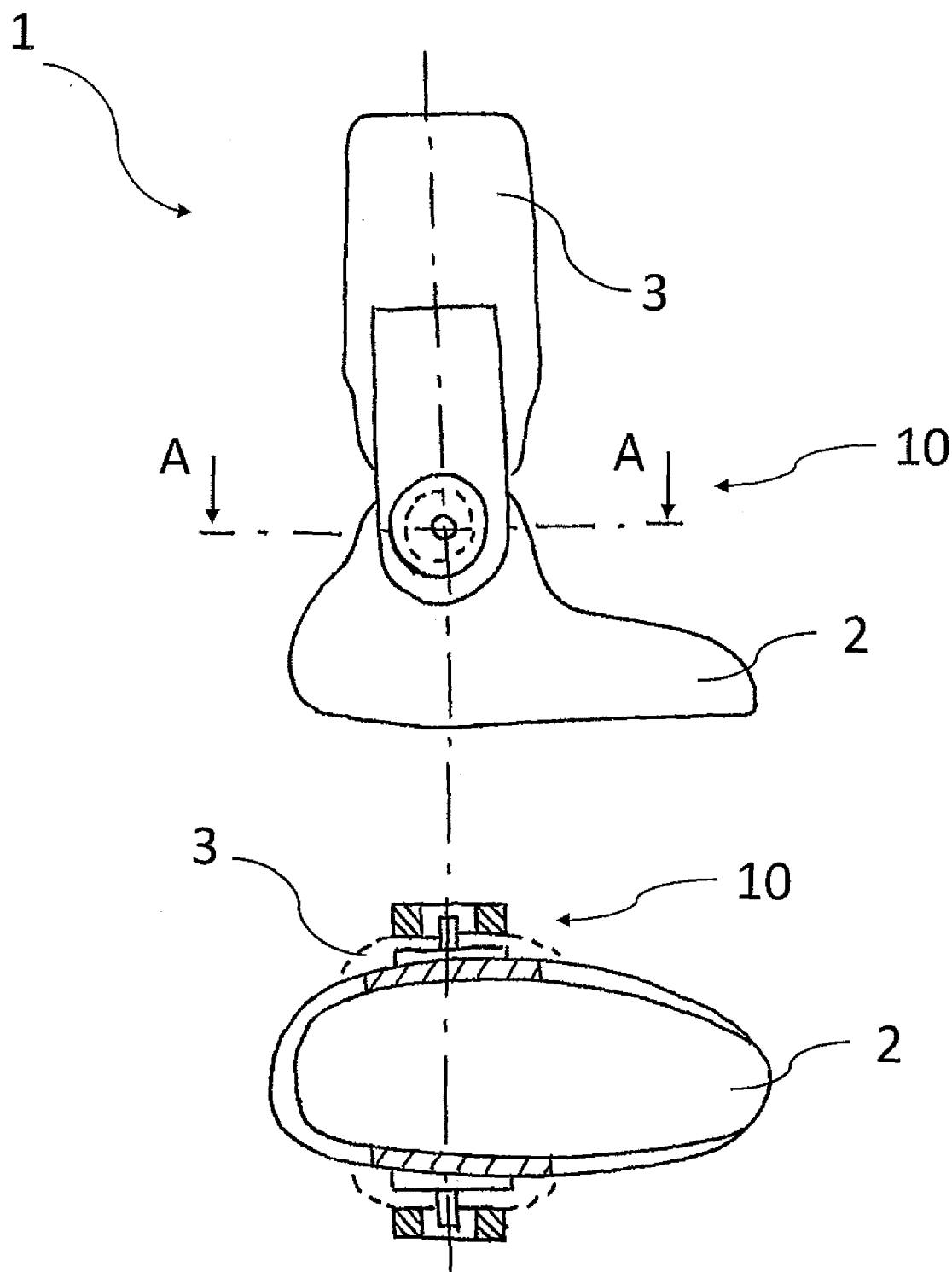


Fig. 3

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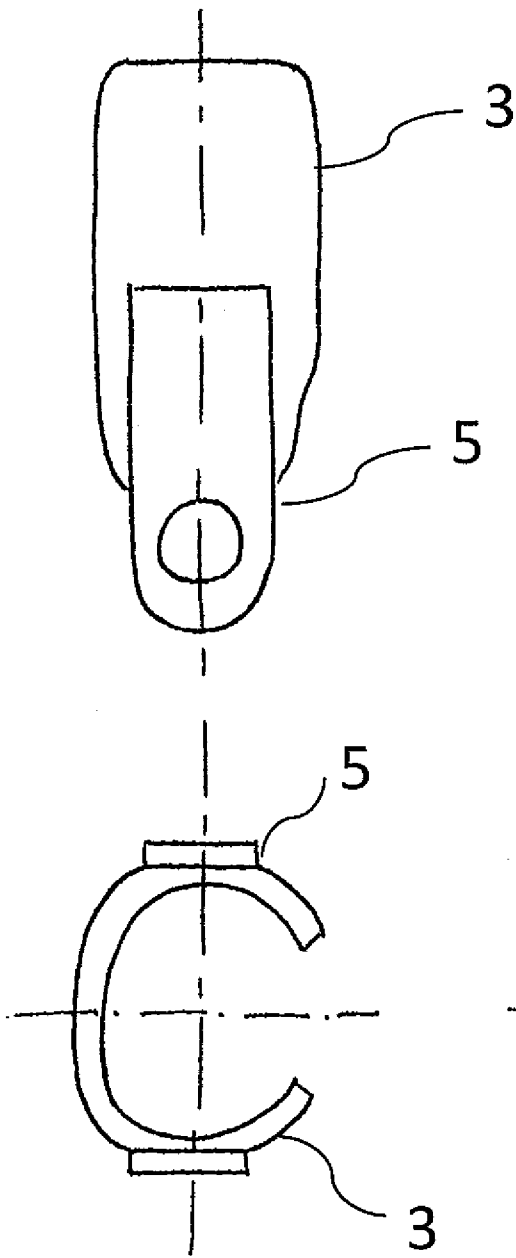


Fig. 4A

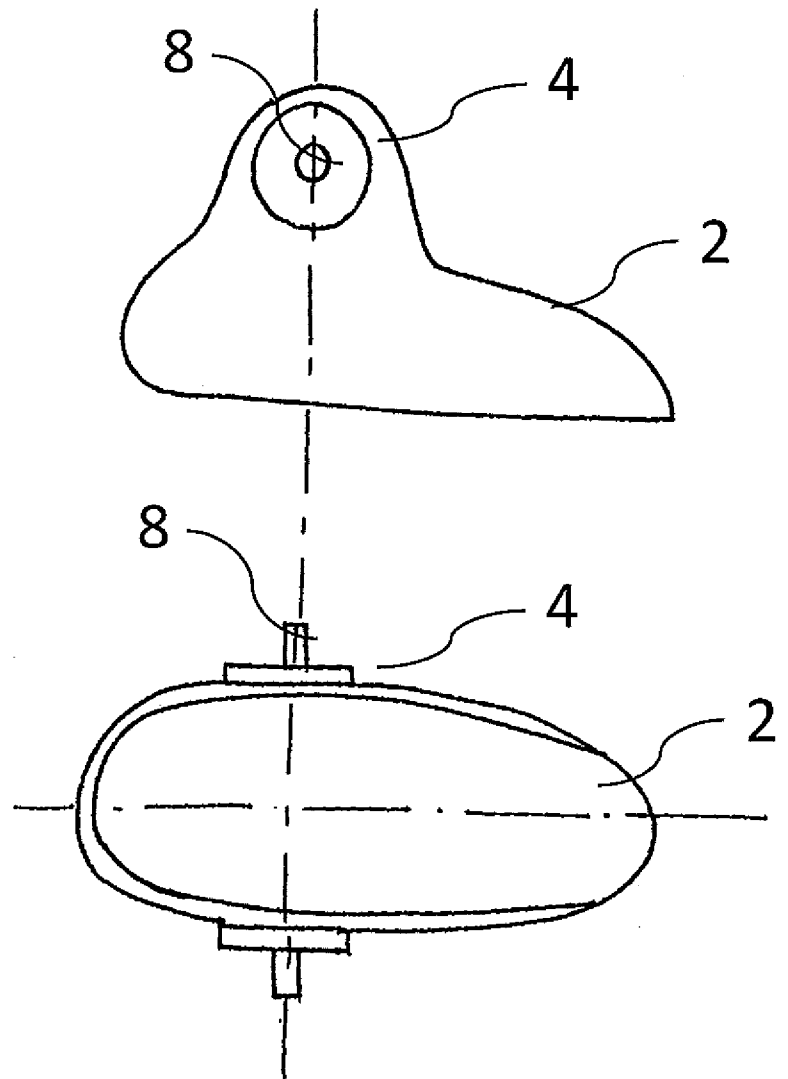


Fig. 4B

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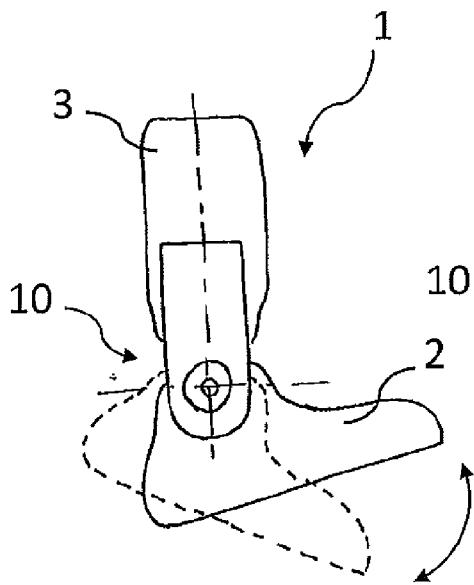


Fig. 5A

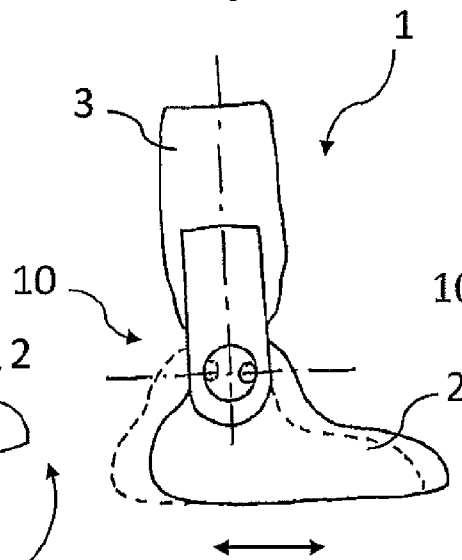


Fig. 5B

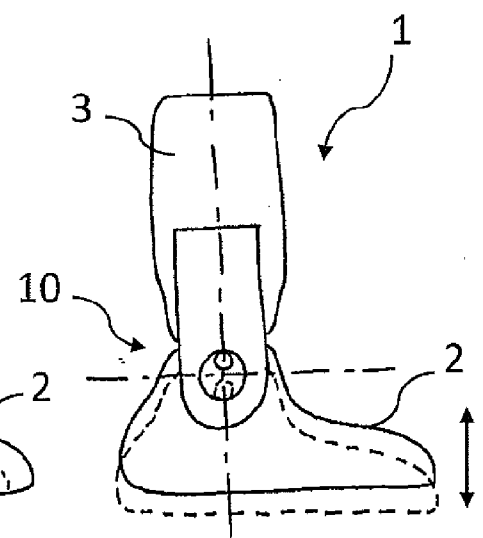


Fig. 5C

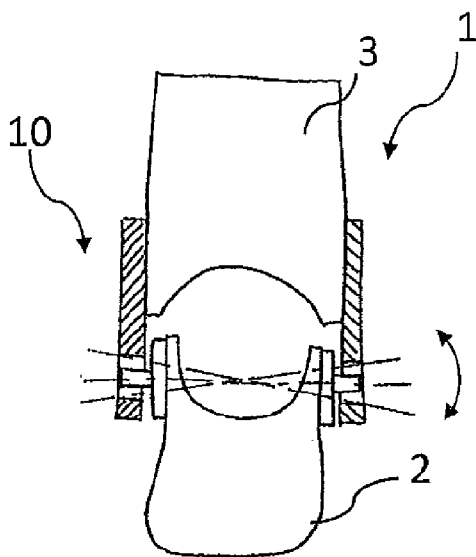


Fig. 5D

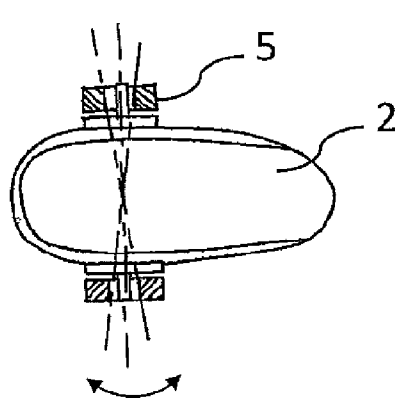


Fig. 5E

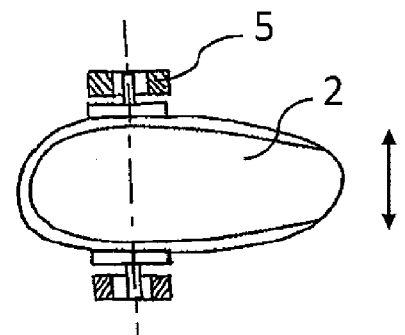


Fig. 5F

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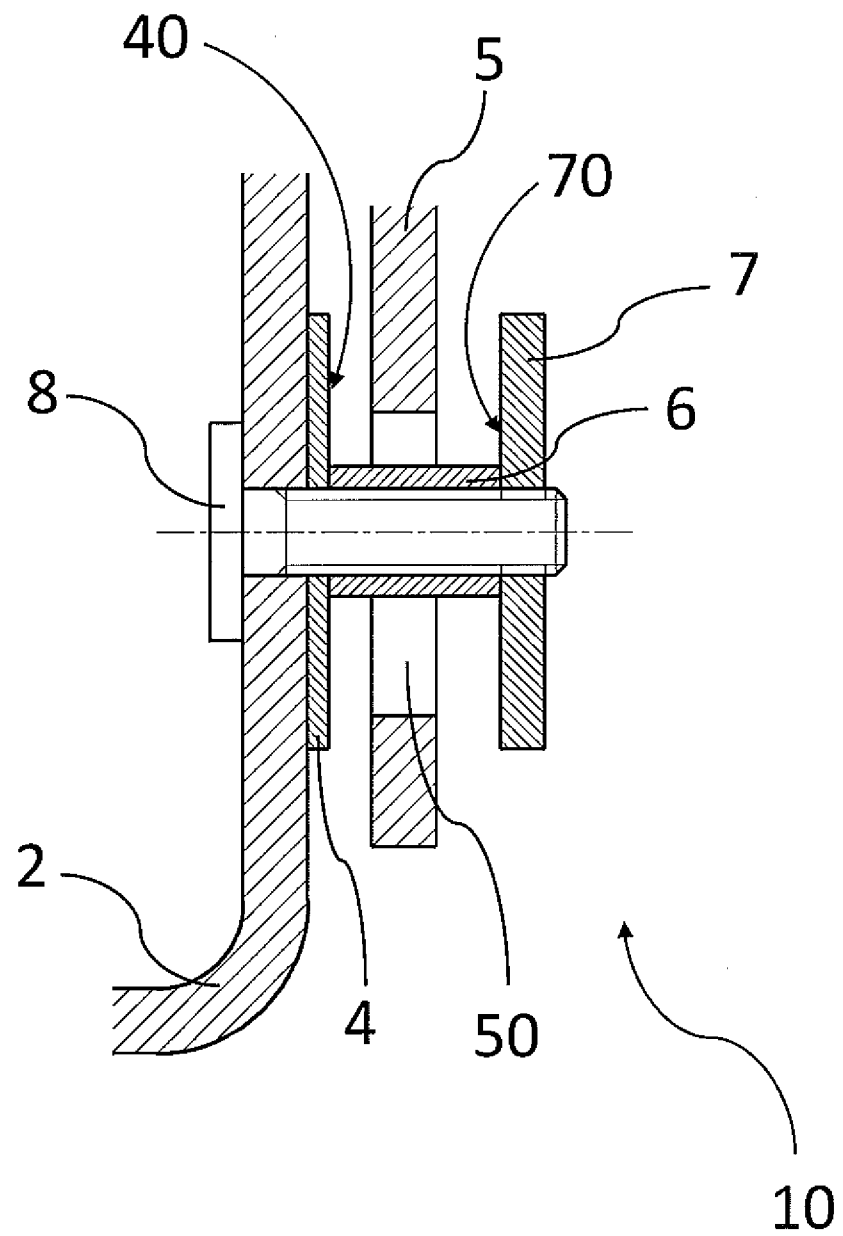


Fig. 6

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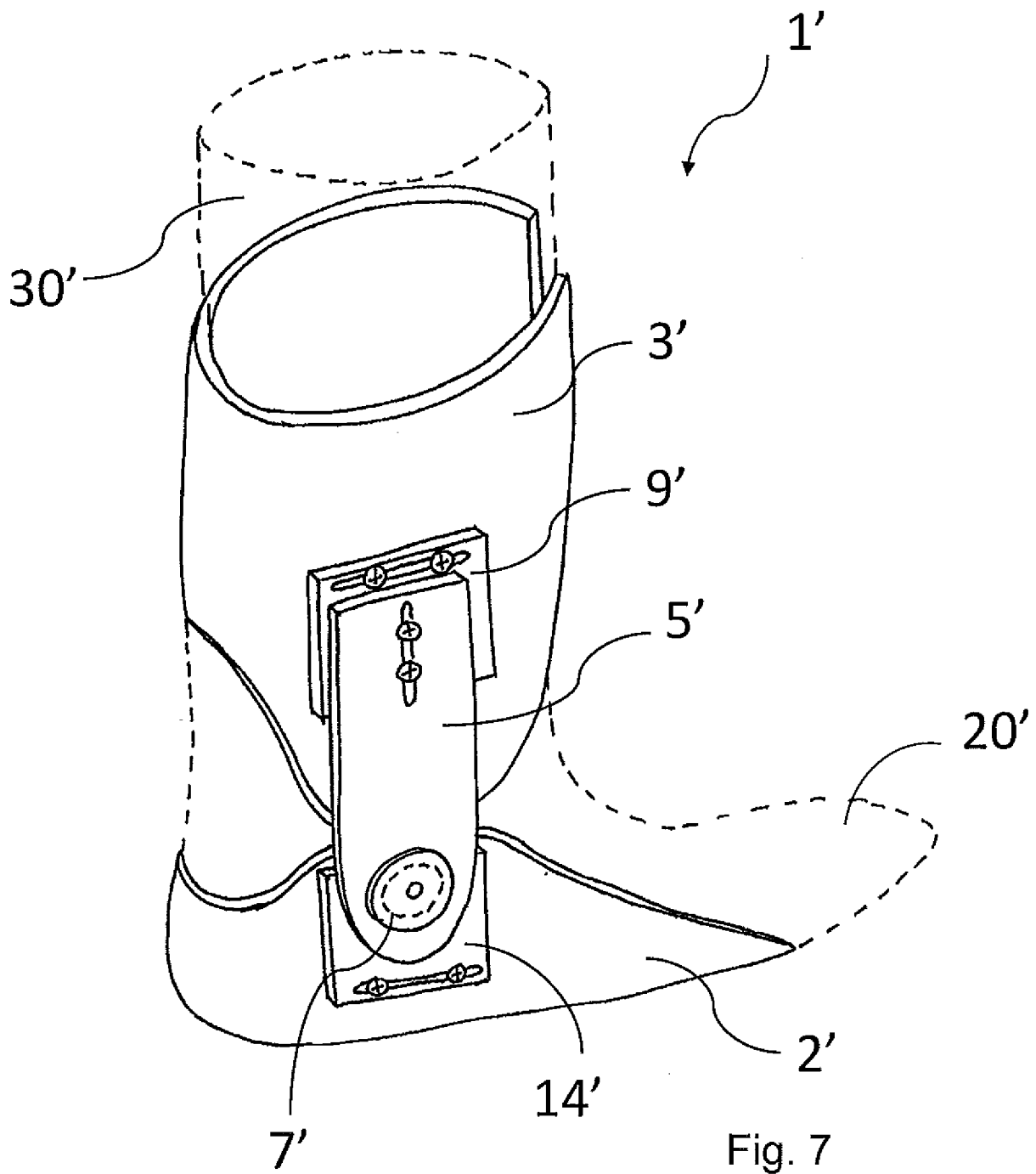


Fig. 7

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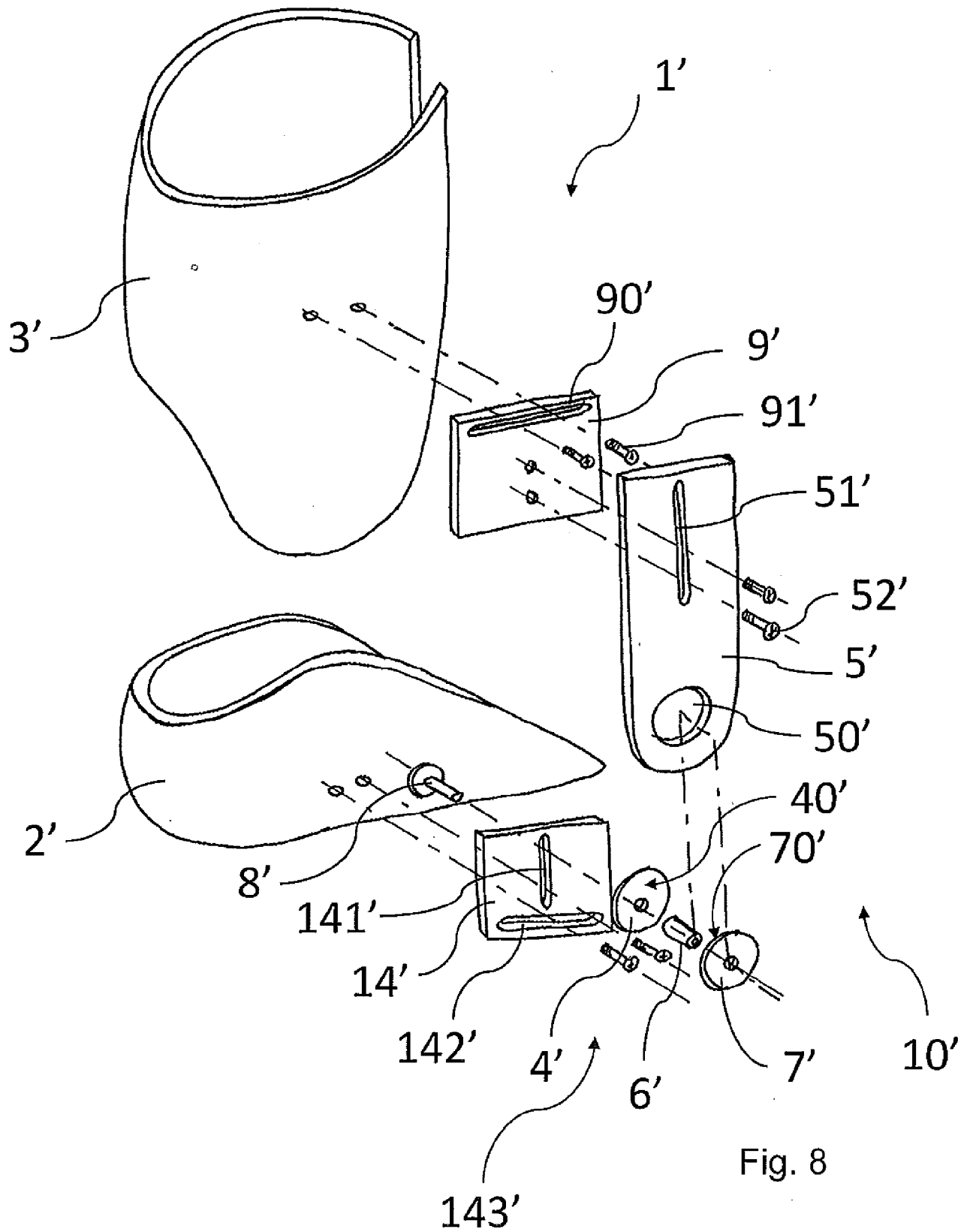


Fig. 8

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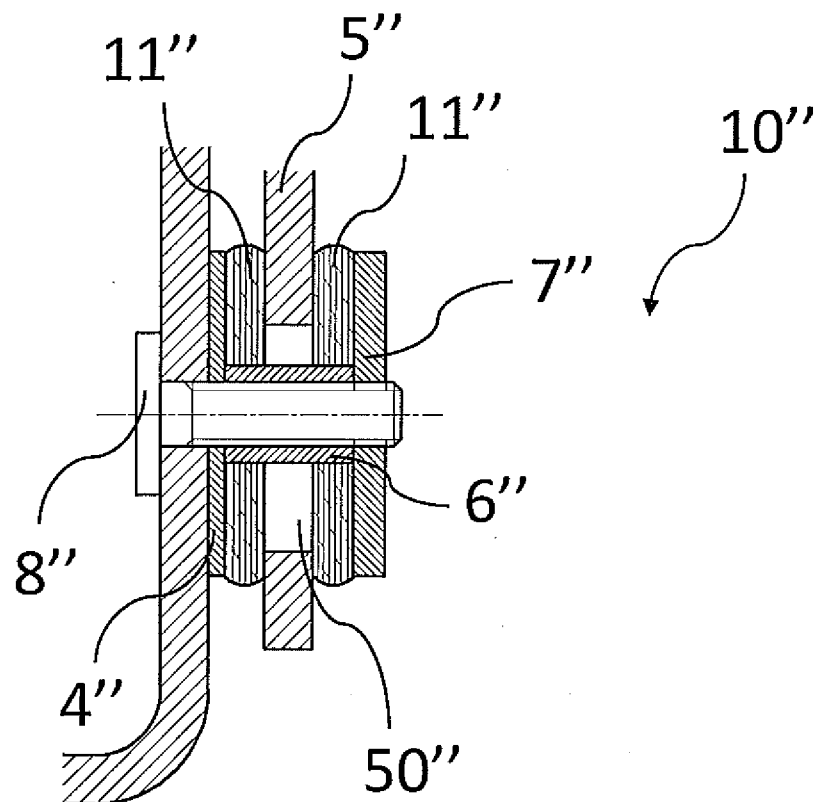


Fig. 9A

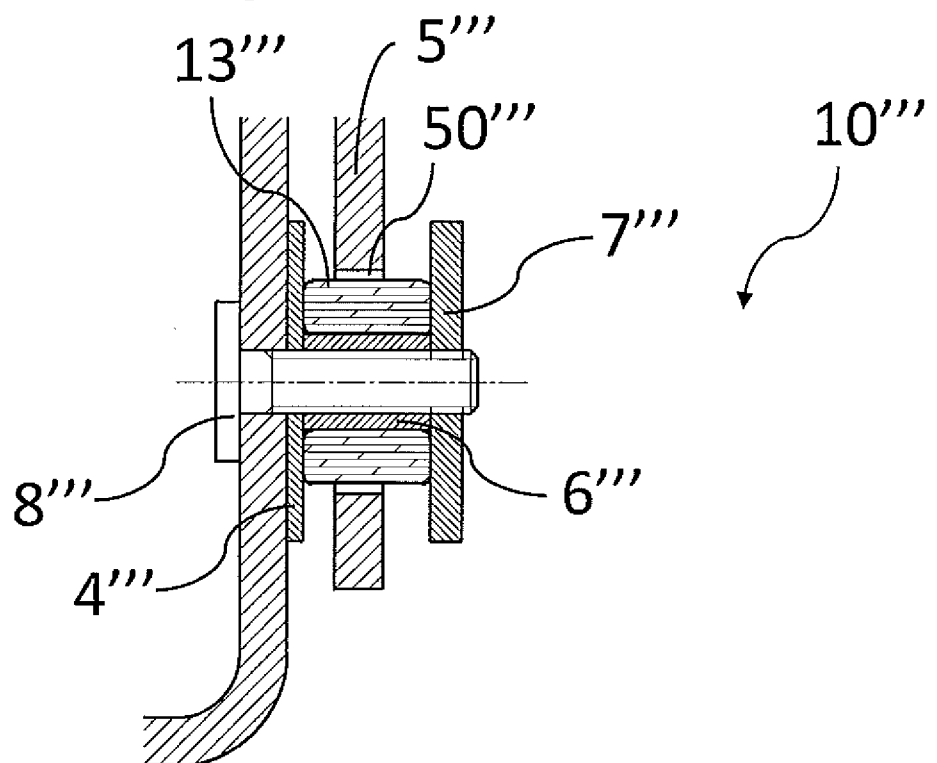


Fig. 9B

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2017/051734

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F5/01
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

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)

EP0-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.
A	US 2005/187505 A1 (CARLSON J M [US]) 25 August 2005 (2005-08-25) paragraphs [0029] - [0037]; figure 3 -----	1-10
A	US 2010/152865 A1 (JONSSON VILHJALMUR FREYR [IS] ET AL) 17 June 2010 (2010-06-17) paragraphs [0007] - [0045]; figures 1-10 -----	1-10
A	US 5 176 623 A (STETMAN JOE G [US] ET AL) 5 January 1993 (1993-01-05) column 8, lines 4-8; figure 7 -----	1-10
A	US 2005/217151 A1 (VALAT GERARD [FR] ET AL) 6 October 2005 (2005-10-06) abstract; figures 1-7 -----	1-10

☐

Further documents are listed in the continuation of Box C.

☒

See patent family annex.

* Special categories of cited documents :

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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

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

17 May 2017

Date of mailing of the international search report

30/05/2017

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Dennler, Samuel

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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