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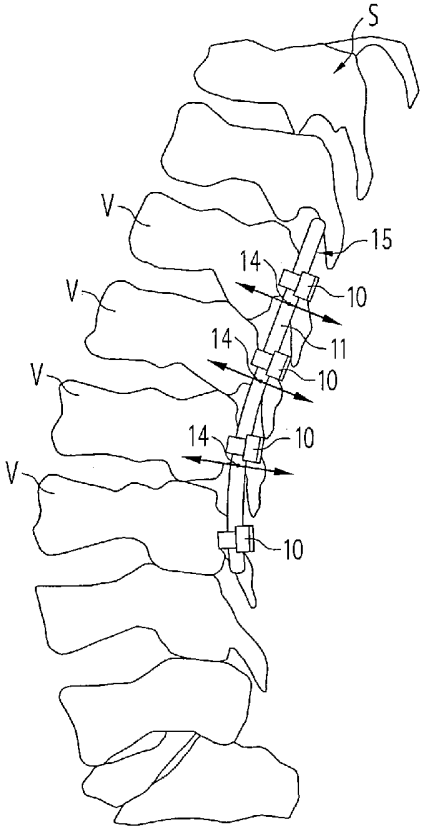
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(54) Title: DEVICE FOR DYNAMIC STABILISATION OF BONES OR BONE FRAGMENTS, ESPECIALLY VERTEBRAE OF THE BACK




(57) Abstract: Device for dynamic stabilisation of bones or bone fragments, especially vertebral bones (V) of the back, having at least one longitudinal member (11) fixable to the vertebrae (V). The longitudinal member (11) is viscoelastically deformable and in each shape state has a predetermined bending resilience.

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"Device for dynamic stabilisation of bones or bone fragments, especially vertebrae of the back"

## Description

The present invention relates to a device for dynamic stabilisation of bones or bone fragments, especially vertebrae of the back, having at least one longitudinal member fixable to the vertebrae.

Principal indications for dynamic, especially posteriorly performed, fixation are age- and/or disease-related decay (degeneration) of the integrity of the spine structures, inflammation and/or injuries in the region of the intervertebral disc, of the ligamentous apparatus, of the facet joints and/or of the subchondral bone.

Posterior dynamic fixation systems have the function of so modifying the pattern of movement in the segment of spine in question that the pain caused by chemical irritation (material of the nucleus in contact with nerve structures) and/or by mechanical irritation (hypermobility) disappears and the metabolism of the structures is preserved or restored.

Clinical experience with existing posterior dynamic fixation systems as described, for example, in EP 0 669 109 B1 and in the manual "Fixateur externe" (authors: B.G. Weber and F. Magerl, Springer-Verlag 1985, page 290-336) shows that it is advantageous for a posterior dynamic fixation system to be flexible in respect of bending and rigid in respect of compression (buckling), shear and rotation. A system must accordingly be dimensioned for maximum deformation with regard to flexion and for maximum loading with regard to buckling, shear and rotation. In order to be able to combine these intrinsically contradictory conditions, it has already been proposed to manufacture the longitudinal members from a biocompatible high-performance plastics material. Because of the very low modulus of elasticity of the high-performance plastics materials compared to titanium and steel, the longitudinal members have to be of relatively thick construction compared to the longitudinal members conventionally manufactured from clinically used metal, which although having a positive effect on the resistance to shear and to buckling is detrimental to flexibility.

In addition, when using conventional biocompatible high-performance plastics material for longitudinal members, it is problematic that the plastics material in the mechanical fixing "creeps

away" at the clamping sites after a relatively short time under the forces occurring therein, with the consequence that re-fixing or even re-implantation becomes necessary.

The possibility of being able to bend longitudinal members is of great importance especially in the case of posterior stabilisation by means of pedicle screws, because the anatomical conditions are often such that the pedicle screws screwed through the pedicles and into the vertebrae are misaligned. In order that the longitudinal members can nevertheless be connected to the pedicle screws in as stress-free manner as possible, it must be possible for the shape of the longitudinal members to be matched *in situ* to the position and orientation of the pedicle screws. In the case of polyaxial pedicle screws, the bending adjustment can be limited to one plane, whereas in the case of monoaxial pedicle screws the longitudinal members have to undergo bending adjustment in three dimensions.

A further constructional form for a dynamic fixation system is proposed in EP 0 690 701 B1. This last-mentioned system comprises a connecting rod, the extremities of which are fixable to two neighbouring vertebrae and which has a curved central portion so that it is resiliently yielding within certain limits. Otherwise, the connecting rod is not modifiable in respect of how it is shaped.

Also, WO 01/45576 A1 proposes a dynamic stabilisation system comprising a longitudinal member having two metallic end portions which are fixable in complementary accommodation apertures within the heads of two neighbouring pedicle screws. Arranged between the two end portions is an articulation member which is resiliently yielding in the longitudinal direction, preferably made of resiliently yielding material. The two end portions of the longitudinal member are rigid. In addition to that articulation member, the arrangement of a resilient band between two pedicle screws is proposed, which extends parallel to the resilient articulation member. Otherwise, in the case of that arrangement too, the articulation member is, in respect of its longitudinal extension, predetermined during manufacture, that is to say it cannot be modified.

Mention should also be made finally of the arrangement according to FR 2 799 949, which is characterised in that the longitudinal member is in the form of a spring element, for example in the form of a leaf spring having a meandering curve shape.

Also, the longitudinal member in the case of the arrangement according to WO 98/22033 A1 comprises a spring element which retains its shape predetermined during manufacture.

Also, EP 1 364 622 A1 describes a resilient stabilisation system for spines which consists of a resiliently flexible connecting element or longitudinal member which can be passed through the apertures of a plurality of pedicle screws having offset aperture axes and anchored. That connecting element or longitudinal member should preferably be made of a resiliently flexible biocompatible material, preferably plastics material. Aromatic polycarbonate-polyurethane is mentioned as being especially advantageous. This is obtainable as a commercial product, for example under the Trade Mark BIONATE® from Polymer Technology Group, 2810 7th Street, Birkly, California 94710 USA and CHRONOFLEX® C from CardioTech International Inc., 78E Olympia Ave., Woburn, MA 01801-2057, USA. The known connecting element or longitudinal member should have sufficient bending resilience about all axes of its cross-section to allow its insertion even into apertures of screw heads that do not lie on one axis but on a line of any desired course or that are naturally offset in various directions because of differing vertebral arrangements.

The integration of spring elements into a longitudinal member of the kind in question herein is also described in GB 2 382 304 A, US 5 480 401, DE 42 39 716 C1, FR 2 827 498 A1, EP 0 919 199 A2 or JP 2002/224131. It is common to all these last-mentioned arrangements, however, that they have a relatively complicated mode of construction, that being the case, more specifically, because the mentioned spring elements are integrated as additional components or structural units. In that prior art, the spring elements are not intrinsic to the longitudinal member.

The present invention is based on the problem of providing a device for dynamic stabilisation of bones or bone fragments, especially vertebrae of the back, having at least one longitudinal member fixable to the vertebrae, which longitudinal member can be matched without complication to the very great variety of situations for implantation without the dynamic being lost and can be firmly fixed lastingly, especially to so-called pedicle screws.

The problem is solved in accordance with the invention by the characterising features of claim 1, advantageous developments and details of the invention being described in the subordinate claims.

The core of the present invention accordingly lies in the fact that the longitudinal member is "viscoelastically" deformable and in each shape state has a predetermined bending resilience. The latter should be imparted especially by a metal portion whereas otherwise the longitudinal

member is made principally of plastics material that is tolerable to humans, especially of polycarbonate-urethane or PCU, as is commercially available, for example, under the Trade Mark BIONATE®. The longitudinal member according to the invention is therefore specifically in the form of a compound construction and consists, on the one hand, of the mentioned plastics material and, on the other hand, of metal that is tolerable to humans, especially titanium or titanium alloy, the plastics material being primarily responsible for the viscous deformability and the metal being primarily responsible for the bending resilience.

As already mentioned, conventional biocompatible plastics materials have the disadvantage that, after being subjected to mechanical pressure for a relatively long period, they yield to that pressure and actually "creep away" under that element of pressure. There is accordingly a risk of the implant becoming loose with obviously disadvantageous consequences. In order to resolve that problem without otherwise losing the afore-mentioned disadvantages, metal is provided, in accordance with the invention, at the clamping sites of the longitudinal member. Clamping is accordingly carried out directly at the metal of the longitudinal member so that the afore-mentioned problem no longer occurs.

Advantageous material properties of the plastics material that is tolerable to humans or biocompatible are described in claims 4 and 5.

Alternatively, besides polycarbonate-urethane (PCU), the plastics portion can also consist of polyurethane, silicone-urethane copolymer or like material or a mixture thereof. The decisive factor is that the parameters mentioned in claims 4 and 5 are present or that the material has similar properties to PCU.

The dimensions and the proportions of plastics material and metal are preferably so selected that the longitudinal member, when held at one extremity, can be resiliently deflected, within a predetermined shape state, about an angle of 5° to 12°, especially about 7° to 9°, over a length which corresponds to the spacing between two neighbouring vertebrae or about 2-5 cm. To be resiliently deflected means that, after deflection, the longitudinal member or the corresponding portion of the longitudinal member restores itself 100 % automatically after deflection.

It should be mentioned at this point that the device according to the invention is in principle also suitable for anterior implantation when it is necessary for the point of rotation of the spine segment in question to be moved anteriorly.

As a result of the compound construction it is also possible to reduce the dimensions of the longitudinal member consisting primarily of high-performance plastics material to a minimum, that is to say for it to be made substantially smaller than a longitudinal member were it to be made exclusively from biocompatible high-performance plastics material.

In addition, the metal portion on the one hand should be so dimensioned that its critical bending angle is greater than/equal to the maximum bending angle of the stabilised vertebrae that is present in association with the dynamic fixation system and on the other hand should be so constructed that the longitudinal member remains dimensionally stable after the *in situ* bending adjustment.

DE 93 08 770 U1 describes a plastics rod having a metal core. That plastics rod serves as a test rod or template in order to be able to match the shape of the longitudinal members to the position and orientation of the pedicle screws in optimum manner. For that purpose it must be possible for the shape of the test rod to be adjusted by hand *in situ* in the patient. The test rod accordingly consists of a soft plastics material (for example, silicone) and a metal rod that can readily be plastically deformed (for example, pure aluminium). When the test rod has the same external diameter as the longitudinal member, the test rod exactly reproduces the shape required for it to be possible to insert the longitudinal member in the pedicle screws in stress-free manner. The present invention differs from the teaching according to DE 93 08 770 U1 on account of the above-defined condition that

a) the at least one longitudinal member is plastically deformable, by application of a prespecified bending force, from a first shape state "A" to a second, alternative shape state "B", the bending force required therefor being substantially greater than the peak forces occurring *in vivo*, and

b) the at least one longitudinal member is, within the particular stable shape states, resiliently flexible, that being the case, more specifically, within the limits set by the mechanical interplay between the fixation system and the segment of spine, which limits define a so-called "resilient flexing range".

The longitudinal member is accordingly so dimensioned that the biocompatible high-performance plastics material can be lastingly plastically deformed using appropriate forces

whilst, in the deformed state, it should have sufficient bending resilience. That bending resilience is imparted to the plastics material by the metal provided in accordance with the invention, which additionally has the advantage and purpose of defining "creep-proof" pressure sites or clamping sites for the longitudinal member.

It should also be mentioned at this point that the longitudinal member should be so constructed that it is as rigid as possible with regard to compression and shear forces occurring *in vivo* and so constructed that the construct consisting of longitudinal member and anchoring means is substantially resistant to torsion. Only then does the longitudinal member according to the invention contribute to the alleviation of pain and to the healing process.

The longitudinal member

- can be in the form of a flat band or strip or, preferably,
- can have a rotationally symmetrical, circular, polygon-like or elliptical cross-section, the cross-section remaining constant over the entire length in the longitudinal direction of the longitudinal member, varying in accordance with a mathematically describable rule and/or changing in abrupt manner. To that extent, as many degrees of freedom as possible should be provided.

In addition, it should be ensured that the longitudinal member is so dimensioned that, in the mentioned "resilient flexing range", the surface stress is always below the dynamic breaking stress. This also applies especially to the individual components of the longitudinal member, that is to say the plastics and metal components.

In addition, the aim is to make available a dynamic stabilisation system that is based on following fundamental considerations:

The purpose in the present case is to develop a dynamic pedicle screw system, suitable for posterior insertion, which does not fuse pathologically changed spine segments but rather supports the particular structures in their function in a controlled manner.

As already mentioned at the beginning, principal indications for a dynamic system are diseases, inflammation and/or injuries in the region of the intervertebral disc, of the ligamentous apparatus, of the facet joints and/or of the subchondral bone. In those situations it is important to modify the loading pattern in the particular area so that the pathological condition at least does not

deteriorate. Healing would be ideal but, at least in the case of degenerative diseases, that is scarcely possible any more.

The aim of the dynamic system being developed is, however, not only to freeze the pathological condition or possibly to bring about healing but to form, together with the structures concerned, a unit which supports the metabolism of the structures.

As soon as a pedicle screw system is inserted from a posterior direction, the point of rotation of the movement segment concerned is automatically displaced from the intervertebral disc in a posterior direction, should it still be so flexible. Posterior displacement of the point of rotation into the region of the posterior facet joints can have the following effects, depending on the pathology:

1. Source of pain "posterior facet joints":

   Depending on the position of the posteriorly displaced centre of rotation relative to the posterior facet joints and on the axial compressibility of the system, movement in the joints is more or less dramatically reduced. By that means, the preconditions are created for a degeneratively changed joint to be able to recover as a result of missing hyaline joint cartilage being replaced at least in theory by fibrous cartilage (Salter's passive motion principle). A precondition of recovery is, however, that the system can be implanted in a stress-free manner.

2. Source of pain "posterior annulus" of the intervertebral disc; lordosis and intervertebral disc height preserved:

   Tears can occur in the posterior annulus as a result of traumatic developments or degenerative changes. These tears often start from the nucleus and penetrate ever further towards the outer, innervated edge of the annulus. Magnetic resonance imaging (MRI) allows identification of pockets of liquid in the region of the afore-mentioned tears. These so-called "hot spots" can be an indication of an inflammatory process in the region of the posterior annulus. Inflammation can occur, *inter alia*, in that region where granulation tissue growing in from the outside and/or nerve endings also meet nuclear material pushing through from the inside through tears in the annulus (physiological pain). The continuous subsequent flow of nuclear material permanently contributes to that inflammation process.

Theoretically, however, inflammation is not absolutely necessary in order to produce pain; rather, the mechanical pressure of a pocket of liquid on afferent nerve endings can alone cause pain. Suitable stabilisation can halt the inflammation process and even trigger healing. This gives rise to the following considerations:

As a result of the posterior displacement of the point of rotation of the spine segment, its range of movement in flexion and extension is dramatically reduced and the axial force acting on the intervertebral disc is uniformly distributed over the whole of the intervertebral disc. As a result, with "global" flexion/extension of the patient, the nuclear material is no longer squeezed to and fro, that is to say less nuclear material, which stimulates the inflammation process, is pressed through tears in the posterior annulus and against the inflammation site. As a result, the preconditions are created for healing of the inflammation and for the start of a repair process.

3. Problem "primary disc hernia":

In a disc hernia a connection exists between the nucleus and the surroundings of the annulus. As a result, nuclear material can subsequently flow continuously through tears in the annulus. In a nucleotomy, the discharged material and also material from the nucleus are removed, the latter to avoid a secondary disc hernia. As a result, the lesion of the posterior annulus is made larger operatively.

In this case too, posterior displacement of the point of rotation of the spine segment reduces subsequent flow of nuclear material. The disc hernia can no longer grow, and discharged material, if it has not already been removed operatively, is encapsulated and is resorbed by the body. A repair process may take place at the posterior annulus.

Accordingly, in the case of a primary disc hernia a dynamic system has the advantage, at least theoretically, that operative intervention can be minimised (it is not necessary to open the epidural space and cause additional damage to the annulus). As a result, optimum conditions can be created for healing and restoration of the function of the intervertebral disc.

4. Source of pain "posterior annulus of the intervertebral disc" (collapse of intervertebral disc):

   Pain in the posterior annulus can be caused by delamination of the annulus. Delamination of the posterior annulus occurs when the nucleus is dehydrated and the intervertebral disc has accordingly collapsed. As a result of the posterior displacement of the point of rotation to the region behind the posterior facet joints, the pressure in the region of the posterior annulus is reduced, which prevents further delamination of the posterior annulus. As a result, the preconditions are created for healing/scarring of the annulus, provided of course that the annulus has an appropriate healing potential.

5. Source of pain "upper plate/subchondral bone":

   Using MRI it is possible to detect changes in the liquid metabolism in the subchondral bone of the vertebrae. In particular, it is also possible to ascertain a sclerotic change in the bony upper plate, which indicates restriction or stoppage of the nutritional supply to the intervertebral disc. A sclerotic change in the upper plate is not readily reversible. The degenerative "downfall" of the intervertebral disc is pre-programmed.

   Another possibility is an increased liquid content, for which there are two explanations:

   a) inflammation in the subchondral region leading to inflammatory pain;

   b) backing-up as a result of "blockage" of the connecting channels in the cartilaginous upper plate of the vertebra (caused by sclerotic changes etc.).

      The first-mentioned inflammation can be overcome by suitable measures provided that the tissue in question is not permanently damaged.

      In the latter case, the elevated pressure in the subchondral bone caused by the backing-up can, at least theoretically, result in mechanical irritation of the afferent nerve endings (mechanical pain). Measures bringing about a reduction in pressure in the subchondral region can at least reduce the mechanical pain if not cause it to disappear completely. However, the cause of the problem can be removed only with difficulty, even in the latter case.

Posterior displacement of the point of rotation to the region behind the posterior facet joints results in reduction of the load not only on the intervertebral disc but also on the subchondral bone located underneath. Accordingly, a suitable dynamic fixation creates the preconditions for the alleviation of pain and, in the case of inflammation in the region of the subchondral bone, even for healing.

6. Source of pain "nerve roots":

Mechanical pressure on the nerve roots results in numbness and muscle weakness radiating out into the lower extremities, but not in pain. Pain (ischialgia etc.) occurs only when inflammation-triggering nuclear material emerges through tears in the posterior annulus and presses on the nerve roots.

In this case too, posterior displacement of the point of rotation of the spine segment reduces the subsequent flow of the nuclear material stimulating the inflammation process. As a result, the preconditions are created for healing of the inflammation and for the start of a certain repair process in the posterior annulus. It is even feasible to remove a disc hernia if there is no continuing flow of new nuclear material.

7. Problem "spinal fracture":

In the case of a spinal fracture, it is usually the cranial vertebra of the segment concerned and the associated intervertebral disc that are affected. With the aid of good blood flow, bone healing of the vertebra no longer constitutes a problem with the fixation techniques of today described at the beginning. Unlike the vertebra, healing of the intervertebral disc is, because of the lack of blood flow, subject to other rules and takes substantially longer. Changing from a rigid posterior fixation to a flexible posterior fixation after about 6 months brings about a reduction in the load on the intervertebral disc and allows certain movement components. Depending on the magnitude of the decrease in load and the remaining scope for movement, the preconditions are created for healing of the intervertebral disc provided that the supply to the intervertebral disc from the subchondral region of the adjacent vertebrae is not impeded (for example, as a result of callus formation in the region of the subchondral bone).

The posterior displacement of the point of rotation of the particular spine segment brought about in the case of a posteriorly implanted dynamic system brings about a reduction in the load on the injured intervertebral disc as already described hereinbefore and, in addition, allows axial deformation, which is important for the nutritional supply to the intervertebral disc.

In the light of the above considerations, it is therefore also an aim of the present invention, as a result of posterior displacement of the point of rotation of an affected spine segment, to immobilise the posterior annulus of the intervertebral disc concerned, with the consequence that posterior outflow of nuclear material is correspondingly reduced, whilst at the same time axial deformation, which is important for the nutritional supply to the intervertebral disc, should be possible, more specifically in such a manner that the intervertebral disc and the associated upper plates are subjected to pressure in substantially homogeneous manner. Accordingly it is also an objective to make available a sufficiently dynamic stabilisation system by means of which the point of rotation of the affected spine segment is displaced in a posterior direction in predetermined manner.

Accordingly, the system according to the invention should also be distinguished firstly by an extremely elegant construction and operation technique and the advantages of a dynamic system, on the one hand, and by the possibility of optimum determination of the posterior point of rotation of a predetermined spine segment, on the other hand.

That problem is solved, in accordance with the invention, by means of the fact that it comprises longitudinal member connecting means by means of which at least two longitudinal member portions can be connected to one another.

Accordingly, from a medical point of view, it can certainly be advantageous for the bone anchorage means, for example pedicle screws, to have longitudinal member accommodation apertures or slots whose axial spacing from the distal extremity located opposite is variable, especially adjustable, so that an appropriately different spacing of the longitudinal member from the vertebra can be set. As a result, for example, the posterior point of rotation can be adjusted individually. The simplest means of putting those considerations into practice consists in keeping a stock of pedicle screws having heads of differing heights, in which the longitudinal member accommodation slots are formed. An alternative means of putting them into practice comprises screw heads whose axial position can be modified relative to the shanks of the

pedicle screws, the screw heads being, for example, screwed onto the shanks of the screws and fixable at different individual heights by means of lock screws.

Another possibility is to hold a supply of pedicle screws having screw heads that can be pushed and/or locked onto the threaded shanks and that have different heights of longitudinal member accommodation apertures. It will be seen then that, once a pedicle screw has been put in place, the operating surgeon no longer will need subsequently to place it deeper or higher (with the risk of its loosening) in order for the longitudinal member to be arranged at the prespecified spacing from the vertebra. He will need only to exchange, or change the height of, the screw head.

An especially elegant embodiment of a device according to the invention is characterised in that the longitudinal member consists of a plastics rod, around which a metal wire, but especially a flat metal band, is helically wound. Preferably, the metal band is embedded in the plastics material. In a specific embodiment, the metal band is embedded in the plastics material in such a manner that it forms, together with the plastics material, a continuously smooth surface. The metal band can have interruptions, for example rows of holes, which are filled with plastics material.

Clamping of the longitudinal member constructed in such a manner is always carried out at locations reinforced, or covered, by the metal band. The longitudinal member is preferably in the form of a solid-construction plastics rod. However, it is also feasible for the longitudinal member to be in the form of a hollow rod or tube.

The metal band winding acts like an outer helical spring, giving the longitudinal member the requisite resilience in the particular deformed state, more particularly a resilience which exceeds that which is intrinsic to the plastics rod.

When the diameter of the longitudinal member is about 6.0 to 8.0 mm, the width of the metal band is about 4.0 to 6.0 mm. The afore-mentioned interruptions then have a diameter of about 2.0 to 3.0 mm.

If the longitudinal member is in the form of a hollow rod or tube, the wall thickness is about 1.5 to 2.0 mm, preferably about 1.5 mm.

In a specific embodiment, the winding of the metal band around the plastics rod is tightly spaced so that the axial spacing between neighbouring turns of metal band is only about 1.5 to 3.0 mm. The winding of the metal band is carried out at an angle of about 15° to 30° relative to the plane extending perpendicular to the longitudinal extent of the longitudinal member, or cross-sectional plane. The metal band consists of titanium or titanium alloy and has a thickness of about 0.2 to 0.4 mm, of course that being dependent, in the final analysis, on the overall dimensions of the longitudinal member.

The end-face extremities of the longitudinal member are preferably limited by metal caps or metal discs. Those end-face metal caps or metal discs can also be connected to one another by means of a wire passing centrally through the longitudinal member, more specifically in such a manner that the end-face metal caps or metal discs can be tensioned with respect to one another in an axial direction. For that purpose, the central metal wire extends through the metal caps or metal discs, more specifically in such a manner that it projects outwards at the end faces, each of those projecting portions having a screw thread so that tensioning nuts can be screwed onto the central metal wire from the outside.

In an alternative embodiment, the longitudinal member is also a plastics rod in which a metal armouring has been embedded. That metal armouring can be constructed in very different ways. In that regard, reference is made to claims 13, 14 ff., 18 ff., 22 ff. and 27 ff.

Corresponding examples embodying a stabilisation system according to the invention will be explained hereinbelow in greater detail with reference to the accompanying drawings, in which:

Fig. 1 is a view from the posterior direction of a spine segment comprising four vertebrae, with posterior stabilisation of that segment;

Fig. 2 is a side view along line 2-2 according to Fig. 1 of the arrangement according to Fig. 1;

Fig. 3 is a diagrammatic side view of a first embodiment of a longitudinal member constructed in accordance with the invention;

Fig. 4 is a diagrammatic side view of a second embodiment of a longitudinal member constructed in accordance with the invention;

Fig. 5 is a diagrammatic side view of a third embodiment of a longitudinal member constructed in accordance with the invention;

Fig. 6 is a perspective view of an end-face end portion of a metal armouring of the longitudinal member according to Fig. 5;

Fig. 7 is a longitudinal section through part of a fourth embodiment of a longitudinal member constructed in accordance with the invention;

Fig. 8 is a diagrammatic cross-section through the embodiment according to Fig. 7;

Fig. 9 is a diagrammatic longitudinal section through a fifth embodiment of a longitudinal member constructed in accordance with the invention; and

Fig. 10 is a model view for the stabilisation system according to the invention in accordance with Fig. 3, which also applies in corresponding manner to the other embodiments.

Figs. 1 and 2 show part of a spine, reference letter "V" denoting the individual vertebrae. Reference letter "S" denotes the spine.

The individual vertebrae "V" have been stabilised posteriorly; more specifically, for that purpose pedicle screws have been screwed into four vertebrae "V" from the posterior direction. The heads of the screws each have accommodation apertures or accommodation slots for accommodating a rod-shaped longitudinal member 11. The longitudinal member is, as can be seen especially from the further figures, of round rod-shaped construction and is fixed by clamping in the heads of the pedicle screws 10. In that manner, a spine segment having four vertebrae "V" can be stabilised. The longitudinal member or members are so designed that they are plastically deformable, by application of a predetermined bending force, from a first stable shape state to a second, alternative stable shape state in accordance with Figs. 1 and 2. However, within that implantation state, the longitudinal members 11 should be resiliently flexible, more specifically within predetermined limits as described in the introduction. As a result, dynamic stabilisation of a predetermined spine segment is achieved together with all the advantages mentioned hereinbefore. The mentioned bending resilience of the longitudinal member(s) 11 is indicated in Fig. 2 by a double-headed arrow 14 and is so dimensioned that,

when the longitudinal member 11 is held at one extremity, it can be resiliently deflected, within a dimensionally stable state, about an angle of about 8° (double-headed arrow 14).

It should be mentioned again at this point that the described device can comprise longitudinal member connecting means, by means of which at least two longitudinal member portions can be connected to one another. The longitudinal member connecting means can have, for example, two longitudinal member accommodation apertures or accommodation slots located opposite one another, into each of which one longitudinal member end portion can be inserted and, by means of a clamping screw or the like, fixed.

The longitudinal member connecting means can be either of rigid or, preferably, of resiliently flexible construction. They allow segment-wise implantation of longitudinal members and highly individual stabilisation of a portion of spine.

From Figs. 1 and 2 it can otherwise also be seen that stabilisation of a portion of spine by means of the device according to the invention is always so carried out that flexibility is present only in respect of flexion and extension. As a result, pressure on the upper plate and intervertebral disc is considerably reduced without losing axial deformation of the intervertebral disc, which is important for the nutritional supply thereof. The described longitudinal member must of course also be so constructed that it can be lastingly deformed using a predetermined force which exceeds anatomical or *in vivo* peak forces. That deformation is carried out outside of the implantation; it should preferably be possible without special ancillary apparatus. Deformation is accordingly carried out "on site" by the operating surgeon.

Both in the longitudinal direction of the longitudinal member and also in the direction transverse thereto, the longitudinal member should be stable, that is to say unyielding, with respect to anatomically usual shear forces. In addition, it is very often desirable for the longitudinal member to be torsion-resistant in order to ensure that extension of the vertebral segment concerned generally occurs substantially only about a posteriorly displaced point of rotation approximately horizontally. As already mentioned hereinbefore, the longitudinal member can be in the form of a flat band or strip. In the embodiments described, longitudinal members in the shape of round rods are implanted or proposed.

With respect to the bending resilience, it should also be mentioned that the angular range mentioned hereinbefore is based on a length of the longitudinal member 11 which corresponds

to the spacing between two neighbouring vertebrae, that is to say a spacing of about 2 - 6 cm, especially about 4 - 5 cm.

Reference numeral 15 denotes the entire stabilisation system shown in Figs. 1 and 2.

In the case of the embodiment according to Fig. 3, the longitudinal member 11 consists of a plastics rod 12, around which a flat metal band 13 is helically wound. The metal band 13 is embedded in the plastics material of the rod 12, more specifically in such a manner that, together with the plastics material, it forms a continuously smooth surface. The metal band moreover has interruptions 16 in the shape of circles or elongate holes, which are likewise filled with plastics material so that a substantially smooth surface of the rod-shaped longitudinal member 11 is produced. With respect to preferred dimensions for a longitudinal member of such a kind reference is made to the statements hereinbefore.

The end-face extremities of the longitudinal member 11 can be, and preferably are, limited by metal caps or metal discs. In the embodiment according to Fig. 3, the end-face limitation is defined by metal caps 17 out from which the helical sheathing of the plastics-comprising rod 12 is then developed.

The plastics rod 12 can also be tube- or tubule-shaped, that is to say hollow. The end faces are closed off by metallic discs or plugs. In the final analysis, the embodiment of the plastics rod is dependent on the application area and also on the requisite dimensional stability and flexibility of the longitudinal member.

Reference numeral 18 denotes the clamping sites of the longitudinal member 11 in Fig. 3. Accordingly, the longitudinal member 11 is clamped in the region of the metallic sheathing. As a result it is possible to avoid the plastics material retreating or "creeping away" under the pressure of a clamping screw after a relatively long period of use. Because the winding of the metal band 13 on the plastics rod 12 is very tightly spaced, the longitudinal member 11 according to Fig. 3 can be clamped at practically any location.

The embodiments yet to be described with reference to Figs. 4 - 9 are all characterised in that the longitudinal member consists of a plastics rod 12 in which metal armouring is embedded. The latter can be, for example, in the form of a round or flat profile having a meandering curve shape, the meandering curves preferably extending to the peripheral surface of the longitudinal

member 11, which otherwise consists of plastics material. In the case of the embodiment according to Fig. 4, the metal armouring is formed by a flat profile 19, which is defined by concatenation of ω-profile elements 20 alternately rotated through 180°. Each of the ω-profile elements 20 extends to the peripheral surface of the longitudinal member 11, which otherwise consists of plastics material, with those parts of the armouring which reach the surface, in conformity with the peripheral surface of the longitudinal member 11, each being rounded in accordance with the cross-sectional periphery of the longitudinal member.

The central members 21 of the ω-profile elements 20 are widened both in the longitudinal direction and in the transverse direction to form support surfaces 22, which are rounded off in the direction transverse to the longitudinal extent of the longitudinal member and integrated flush into the peripheral surface 24 of the longitudinal member 11. The outer surfaces 23 of the connecting members 24 of the ω-profile elements 20 are likewise rounded off in each case in the direction transverse to the longitudinal extent of the longitudinal member 11 so that they can be integrated flush into the peripheral surface of the longitudinal member 11. The longitudinal member 11 according to Fig. 4 is clamped or fixed at the metal surfaces of the central member 21 and connecting member 24, which are flush with the peripheral surface of the longitudinal member 11. In that regard, Fig. 4 shows, in diagrammatic manner, on the one hand, the so-called "best case" and, on the other hand, the "worst case". The "best case" situation is indicated in Fig. 4 by the clamps 25. The "worst case" situation corresponds to the relative position of the clamps 25' in Fig. 4.

Otherwise, the flat profile 19 is constructed with a waisted cross-section.

In the plane of the sheet of the drawing, the metal armouring 19 according to Fig. 4 is relatively flexible, or resilient in flexion. In the plane perpendicular to the sheet of the drawing, the flat profile 19 is relatively rigid. Accordingly, therefore, there is a preferred plane of deformation, which has to be taken into account on implantation.

In the case of the embodiment according to Figs. 5 and 6, the metal armouring comprises three metal wires 26, which extend parallel to the longitudinal direction of the longitudinal member 11 and at the same angular spacing from one another (see Fig. 6) and which are fixed at the end faces through star-shaped discs 27, especially being shrunk into corresponding through-holes. In Fig. 6, reference numeral 28 denotes those through-holes.

Held between the three metal rods 26 are a plurality of disc-shaped supporting elements 29, each of which extends to the peripheral surface of the longitudinal member 11, which otherwise consists of plastics material. The supporting elements 29 are spaced apart from one another in the axial direction, and, in particular, preferably spaced apart equally from one another. The intermediate space is filled by plastics material. The longitudinal member 11 is a round rod of biocompatible high-performance plastics material, for example PCU, having armouring in accordance with Fig. 5 and 6. The disc-shaped supporting elements 29 have, at their edges, three recesses 30, through which the metal rods 26 extend. The three recesses are each arranged distributed uniformly around the periphery of the supporting discs 29.

The metal rods 26, embedded in the plastics material, each extend close to the peripheral surface of the longitudinal member 11. In this case too, the metal rods serve to ensure the bending resilience in a predetermined stable shape state of the longitudinal member 11. For better anchorage between the plastics material and metal it is also feasible for the surface of the metal rods 26 to be roughened.

The embodiment according to Figures 7 and 8 is characterised in that the metal armouring comprises at least one central metal rod 31, which extends parallel to the longitudinal direction of the longitudinal member 11 and on which metal sleeves 32 are mounted, the metal sleeves 32 having, at their end faces respectively facing one another, two, in this case three, longitudinal recesses 33 arranged distributed uniformly around the periphery, into which recesses 33 longitudinal elements 34 formed therebetween of a directly neighbouring metal sleeve 32 can be inserted so that neighbouring metal sleeves 32 can, if required, be pushed into one another, offset at an angle to one another, on the at least one metal rod 31, as shown in Fig. 7. The angular offset between neighbouring metal sleeves can be seen very clearly from Fig. 8.

Between the end-face longitudinal recesses 33 of the metal sleeves 32, spaced away from the free extremity, the longitudinal elements 34 are connected to one another by a central, especially star-like, connecting element 35, the connecting element 35 having a central longitudinal hole 36 for accommodation of the central rod 31, on which the metal sleeve or sleeves 32 can be mounted. The metal sleeves 32 accordingly form, in the region of end faces inserted into one another, a kind of articulated connection 37, which allows bending of the longitudinal member 11 within predetermined limits.

The external diameter of the metal sleeves 32 otherwise corresponds to the external diameter of the plastics portion of the longitudinal member 11. The sleeves 32 are embedded in the plastics material. Preferably, however, the external diameter of the metal sleeves 32 corresponds to the external diameter of the plastics-comprising longitudinal member 11 so that the external peripheral surfaces of the metal sleeves 32 and longitudinal elements 34 are an integral part of the peripheral surface of the longitudinal member 11. The longitudinal member 11 according to Figs. 7 and 8 can be lastingly fixed, that is to say firmly clamped, in the region of those metal sleeves, preferably directly next to an articulated connection.

Fig. 9 shows a fifth embodiment of a device according to the invention, wherein the metal armouring comprises three metal rods 31 extending parallel to the longitudinal direction of the longitudinal member 11, one of the extremities of two of the metal rods being fixed, especially welded, to one of the two end-face end caps 38, more specifically the right-hand end cap 38 in Fig. 9, whilst the other, in that case free, extremity of each is embedded in the plastics material 39. The third rod 31, namely the middle rod in Fig. 9, is fixed to the other end cap 38, namely the left-hand end cap 38 in Fig. 9. The right-hand, free extremity of that metal rod is, in contrast, accommodated, floating, in the plastics material 39. The free extremities of the metal rods 31 each have a thickened portion 40, the thickened portions of the upper and lower metal rods 31 in Fig. 9 being formed to make a connection of the free extremities of those two metal rods. The thickened portion 40 promotes embedding in the plastics material and the damping action of the latter on resilient deformation of the longitudinal member 11. In this context it is to be noted that the longitudinal member according to the invention is constructed according to the so-called Kelvin-Voigt model. The longitudinal members 11 shown constitute a modified Kelvin-Voigt model, in particular having a serially appended resilient element (spring element).

Otherwise it can be seen from Fig. 9 that the respective free extremities of the metal rods 38 are embedded in the plastics material 39 within sleeve-like portions 41 of the end-face end caps 38 of the longitudinal member 11.

Finally, it should also be mentioned that the end-face end caps 38 in Fig. 9, or 27 in Fig. 6, of the longitudinal member 11 can be tensioned with respect to one another in the axial direction. That is no more to be seen in Fig. 9 than in Fig. 6. However, it should be mentioned at this point that this mechanical alternative is feasible.

In the embodiments shown, the metal rods 26, 31 (38) each have a constant diameter over their length. However, it is feasible for the diameter to vary over the length, for example decreasing or increasing continuously or in stepwise manner towards the middle of the longitudinal member 11 or *vice-versa*.

Otherwise it should also be mentioned in respect of Fig. 9 that, in that case too, between the two end caps of the metal rods 31 there are held supporting elements 29 corresponding to those according to Figs. 5 and 6. Clamping of the longitudinal member 11 can take place at those supporting elements 29, and also in the region of the end caps 38, without there being a risk of that clamping becoming loose after a relatively long period of use. The supporting elements 29 also have the function of metal wire spacer elements, that is to say they keep the metal wires at a constant spacing from one another over their length. That spacing is maintained even after plastic deformation of the longitudinal member 11. As a result, a defined "flexing" of the longitudinal member is also obtained after deformation thereof.

In addition to its viscous deformation property, the biocompatible high-performance plastics material used herein also has especially the property of having a shock-absorbing action.

Finally, it should also be mentioned that it is important for the plastics material to prevent the formation of openings in the longitudinal member into which tissue could grow. That is to be avoided. The longitudinal member 11 is, in the case of all the embodiments described, a round rod having a smooth surface. The plastics material used is preferably transparent so that the metal armouring is visible. As a result it can also be seen at which sites the longitudinal member11 can be tightly clamped.

Fig. 10 shows the fundamental difference between the system according to the invention (the right-hand illustration in Fig. 10) and the prior art (the left-hand and middle illustrations in Fig. 10) using the so-called Kelvin-Voigt model. In the case of the prior art according to the left-hand illustration in Fig. 10, the longitudinal member or connecting rod consists of, for example, titanium or a titanium alloy. Such a rod comprises both a flexing or spring component and also a damping component, with both components being in parallel connection with respect to one another. When, instead of titanium or the like, plastics material, for example PCU, is used, a further flexing component is added in series to the two afore-mentioned components (middle illustration in Fig. 10). In accordance with the invention, yet another flexing component is introduced, in parallel, to the last-mentioned model (right-hand illustration in Fig. 10).

This last-mentioned model very clearly represents the "recoiling" effect that is important for the composite according to the invention. The spring in each of the two Kelvin-Voigt models according to the left-hand and middle illustrations of Fig. 10 in parallel connection to the damper does, of course, also result in a certain "recoiling" effect. According to mechanical tests with PCU material, that effect is relatively slow. Recovery of the PCU material takes several hours. By means of the metal component in parallel connection to the PCU material, for example the metal spiral according to Fig. 3, the "recoiling" effect of the PCU material can be accelerated to a greater or lesser degree depending on the material selected and on the geometry of the metal component.

All features disclosed in the application documents are claimed as being important to the invention insofar as they are novel on their own or in combination compared with the prior art.

## List of reference symbols

| | |
|---|---|
| V | vertebra |
| S | spine |
| 10 | pedicle screw |
| 11 | longitudinal member |
| 12 | plastics rod |
| 13 | metal collar |
| 14 | double-headed arrow |
| 15 | stabilisation system |
| 16 | interruption |
| 17 | metal cap |
| 18 | circular surface |
| 19 | flat profile |
| 20 | ω-profile elements |
| 21 | central member |
| 22 | support surface |
| 23 | outer surface |
| 24 | connecting member |
| 25 | clamp |
| 25' | clamp |
| 26 | metal rod |
| 27 | metal disc |
| 28 | through-hole |
| 29 | supporting or spacer element |
| 30 | recess |
| 31 | metal rod |
| 32 | metal sleeve |
| 33 | longitudinal recess |
| 34 | longitudinal element |
| 35 | connecting element |
| 36 | longitudinal hole |
| 37 | articulated connection |
| 38 | end cap |

39 plastics material

40 thickened portion

41 sleeve-like portion

"Device for dynamic stabilisation of bones or bone fragments, especially vertebrae of the back"

## Claims

1. Device for dynamic stabilisation of bones or bone fragments, especially vertebral bones (V) of the back, having at least one longitudinal member (11) fixable to the vertebrae (V), characterised in that
the longitudinal member (11) is viscoelastically deformable and in each shape state has a predetermined bending resilience.

2. Device according to claim 1,
characterised in that
the longitudinal member is a compound construction of, on the one hand, biocompatible high-performance plastics material and, on the other hand, biocompatible metal, especially titanium or titanium alloy, the plastics material being primarily responsible for viscous deformability and the metal being primarily responsible for the resiliently flexible deformability.

3. Device according to claim 2,
characterised in that
at least at the clamping sites of the longitudinal member (11) metal is so provided that a clamping element is supported directly at the metal of the longitudinal member.

4. Device according to one of claims 1 to 3,
characterised in that
the biocompatible plastics material has the following properties:

| | |
|---|---|
| tensile strength at 50 % elongation | about 650 - 5500 psi |
| tensile strength at 100 % elongation | about 900 - 6000 psi |
| ultimate tensile strength | about 6500 - 11000 psi |
| ultimate limit of elongation | about 250% - 600% |
| modulus of elasticity | about 4000 - 270000 psi |
| bending stress on 5 % deflection | about 150 - 11000 psi. |

5. Device according to claim 4,
characterised in that
the plastics material has a temperature expansion coefficient (x $10^6$) of 90/°C to 150/°C.

6. Device according to one of claims 1 to 5,
characterised in that
the plastics portion consists of
polycarbonate-urethane,
polyether-urethane,
silicone-urethane copolymer or like material or a mixture thereof.

7. Device according to one of claims 1 to 6,
characterised in that
the longitudinal member (11) of holding at one extremity, can be resiliently deflected, within a predetermined shape state, about an angle of 5° to 12°, especially about 7° to 9°, over a length which corresponds to the spacing between two neighbouring vertebrae or about 2-5 cm.

8. Device according to one of claims 1 to 7,
characterised in that
the longitudinal member (11) consists of a plastics rod (12), around which a metal wire, especially a metal band (13), is helically wound.

9. Device according to claim 8,
characterised in that
the metal band (13) is embedded in the plastics material in such a manner that it forms, together with the plastics material, a continuously smooth surface.

10. Device according to claim 8 or 9,
characterised in that
the metal band has interruptions (16), which are filled with plastics material.

11. Device according to one of claims 8 to 10,
characterised in that
the end-face extremities of the longitudinal member (11) are limited by metal caps (17) or metal discs.

12. Device according to one of claims 1 to 11,
characterised in that
the longitudinal member (11) consists of a plastics rod (12) in which a metal armouring has been embedded.

13. Device according to claim 12,
characterised in that
the metal armouring is a round or flat profile having a meandering curve shape, the meandering curves of which preferably extend to the peripheral surface of the longitudinal member (11), which otherwise consists of plastics material.

14. Device according to claim 12,
characterised in that
the metal armouring is formed by a flat profile (19), which is defined by concatenation of ω-profile elements (20) alternately rotated through 180°.

15. Device according to claim 14,
characterised in that
each of the ω-profile elements (20) extends to the peripheral surface of the longitudinal member (11), which otherwise consists of plastics material.

16. Device according to claim 14 or 15,
characterised in that
the central members (21) of the ω-profile elements (20) are widened at their extremity to form support surfaces (22), which are rounded off in the direction transverse to the longitudinal extent of the longitudinal member (11) and which are preferably integrated flush into the peripheral surface of the longitudinal member (11).

17. Device according to one of claims 14 to 16,
characterised in that
the outer surfaces (23) of the connecting members (24) of the ω-profile elements (20) are rounded off in each case in the direction transverse to the longitudinal extent of the longitudinal member (11) so that they can be integrated flush into the peripheral surface of the longitudinal member (11).

18. Device according to claim 12,
characterised in that
the metal armouring comprises at least one, especially three, metal rods (26), which extend parallel to the longitudinal direction of the longitudinal member (11) and at the same angular spacing from one another and which are fixed at the end faces through circular or star-shaped discs (27) of metal.

19. Device according to claim 18,
characterised in that
disc-shaped supporting and spacer elements (29) are held by the at least one, especially three, metal rods (26), the external diameter of which elements corresponds to the external diameter of the longitudinal member (11), which otherwise consists of plastics material.

20. Device according to claim 19,
characterised in that,
when there are three or more metal rods (26), the disc-shaped supporting elements (29) have, at their edges, recesses (30), through which the metal rods (26) extend.

21. Device according to claim 20,
characterised in that,
when there are three or more metal rods (26), the rods, embedded in the plastics material, extend close to the peripheral surface of the longitudinal member (11).

22. Device according to claim 12,
characterised in that
the metal armouring comprises at least one central metal rod (31), which extends parallel to the longitudinal direction of the longitudinal member (11) and on which metal sleeves (32) are mounted, the metal sleeves (32) having, at their end faces respectively facing one

another, two or more, especially three, longitudinal recesses (33) arranged distributed uniformly around the periphery, into which recesses (33) longitudinal elements (34) formed therebetween of a directly neighbouring metal sleeve (32) can be inserted so that neighbouring metal sleeves (32) can, if required, be pushed into one another, offset at an angle to one another, on the at least one metal rod (31).

23. Device according to claim 22,
characterised in that,
between the end-face longitudinal recesses (33) of the metal sleeves (32), spaced away from the free extremity, the longitudinal elements (34) are connected to one another by a central, especially star-like, connecting element (35).

24. Device according to claim 23,
characterised in that
the connecting element (35) has a central longitudinal hole (36) for accommodation of a central metal rod (31), on which the metal sleeve or sleeves (32) can be mounted.

25. Device according to one of claims 22 to 24,
characterised in that
the metal sleeves (32), in the region of end faces inserted into one another, define a kind of universal joint connection (37), which allows bending of the longitudinal member (11) to all sides within predetermined limits.

26. Device according to one of claims 22 to 24,
characterised in that
the external diameter of the metal sleeves (32) corresponds to the external diameter of the longitudinal member (11), which otherwise consists of plastics material.

27. Device according to claim 12,
characterised in that
the metal armouring comprises at least two, especially three, metal rods (38) extending parallel to the longitudinal direction of the longitudinal member (11) and at the same angular spacing from one another, one of the extremities of the rods being fixed alternately to an opposite end-face end cap (38) or end disc of the longitudinal member (11), whilst the other,

in that case free, extremity of each is embedded, likewise alternately, in the plastics material (39).

28. Device according to claim 27,
characterised in that
the free extremities of the metal rods (38) each have a thickened portion (40) or are connected to one another to form a correspondingly enlarged thickened portion (40) in order to obtain improved embedding of the longitudinal member (11) in the plastics material.

29. Device according to claim 27 or 28,
characterised in that
the respective free extremities of the metal rods (38) are embedded in the plastics material (39) within sleeve-like portions (41) of the end-face end caps (38) of the longitudinal member (11).

30. Device according to one of claims 18 to 29,
characterised in that
the end-face end caps or end discs (27; 38) of the longitudinal member (11) can be tensioned with respect to one another in the axial direction.

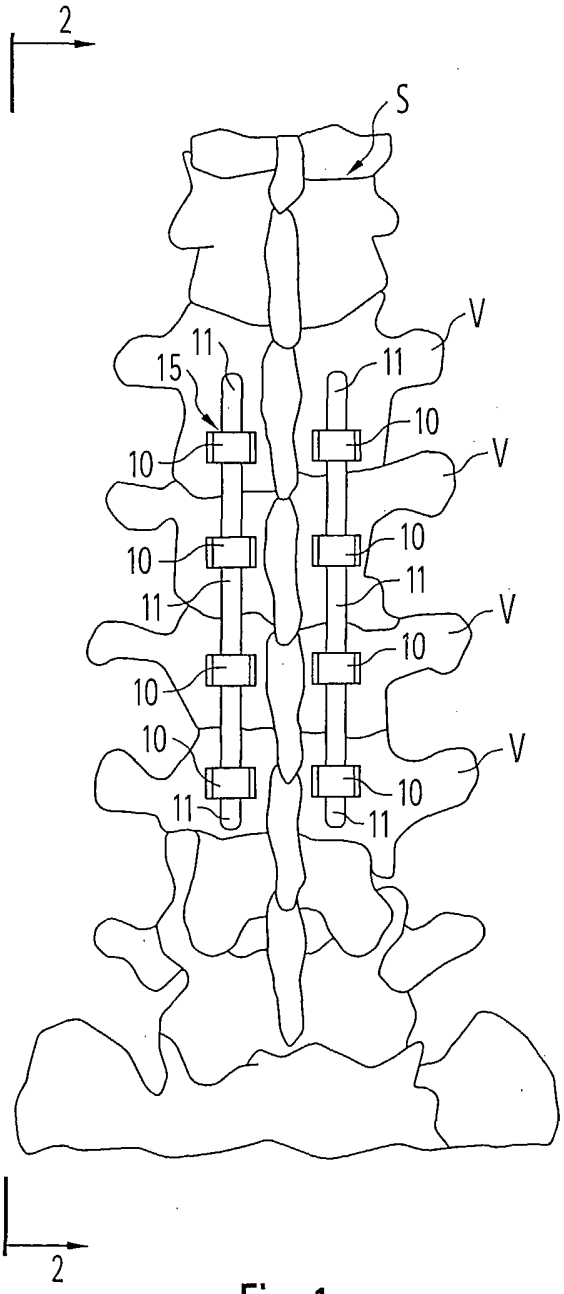



Fig. 1

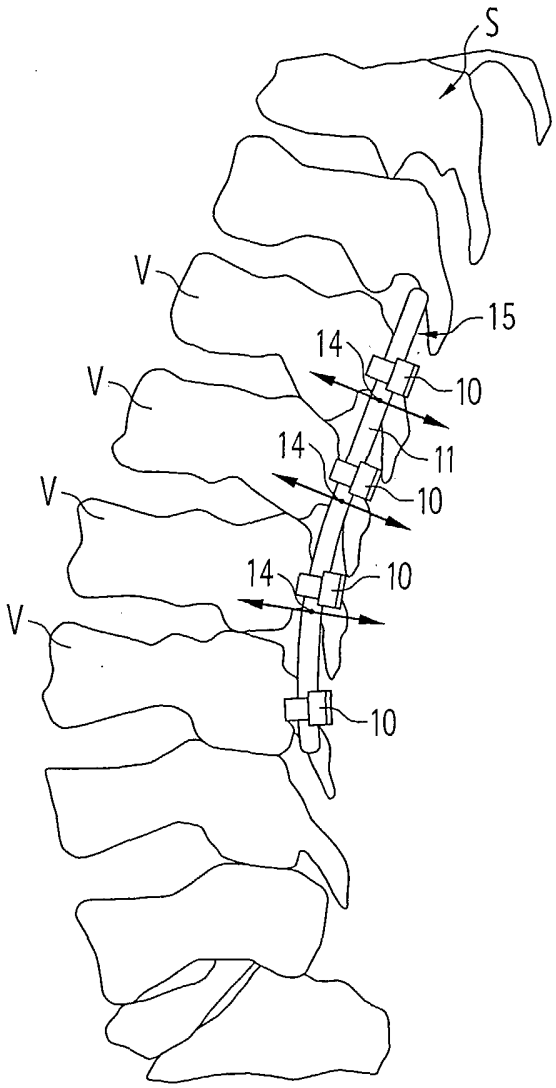



Fig. 2

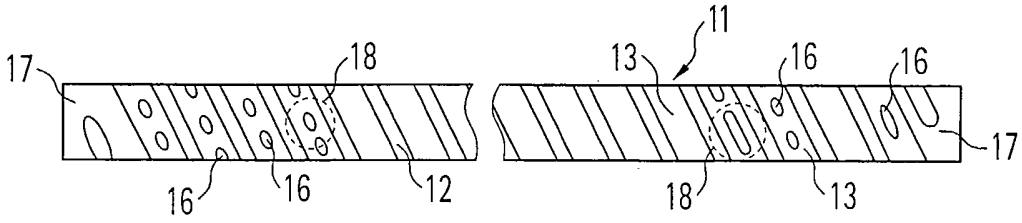



Fig. 3

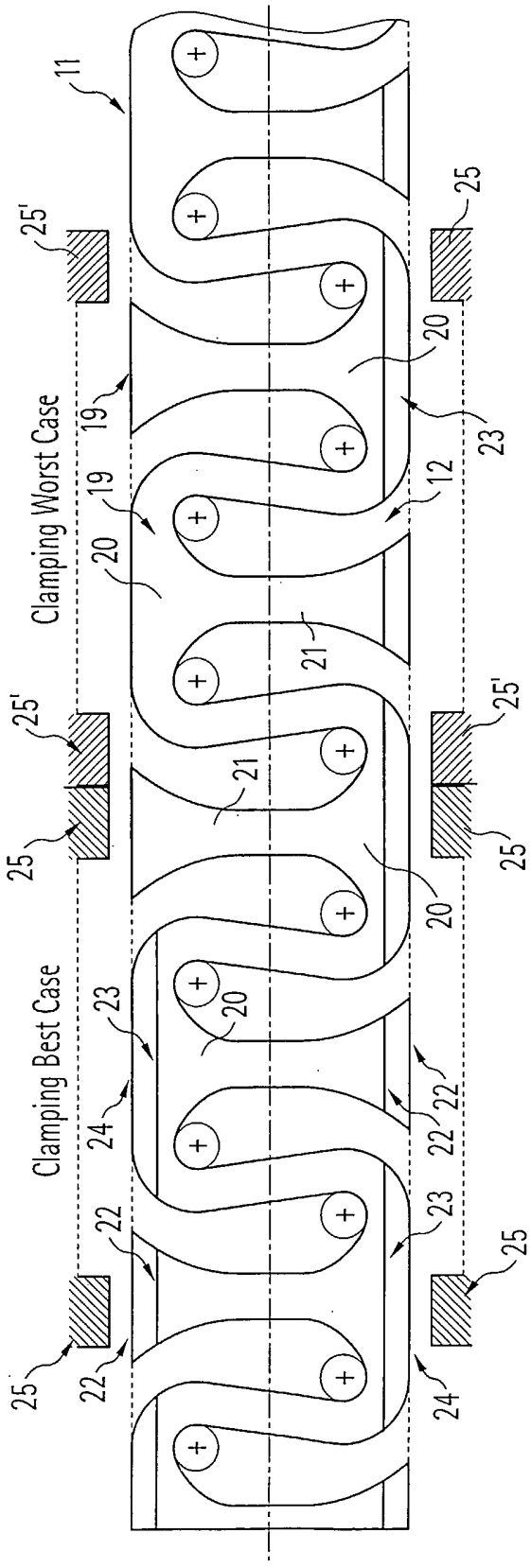

11
25'
25
19
20
23
12
Clamping Worst Case
21
Clamping Best Case
24
22

Fig. 4

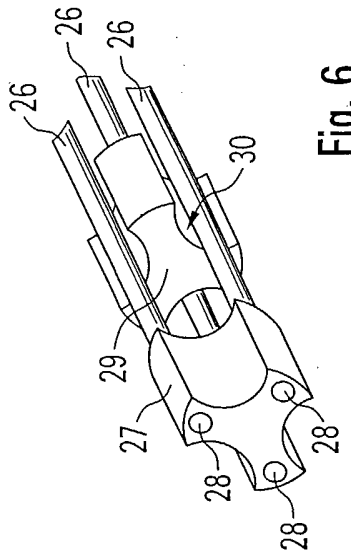



Fig. 6

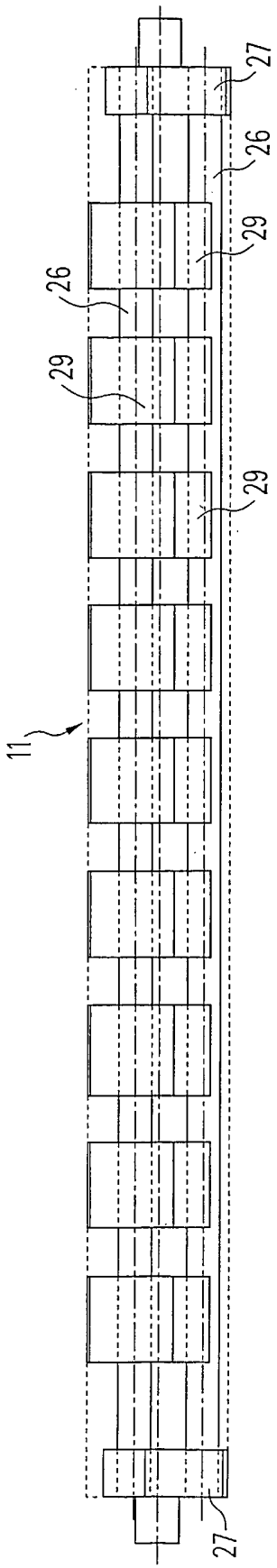



Fig. 5

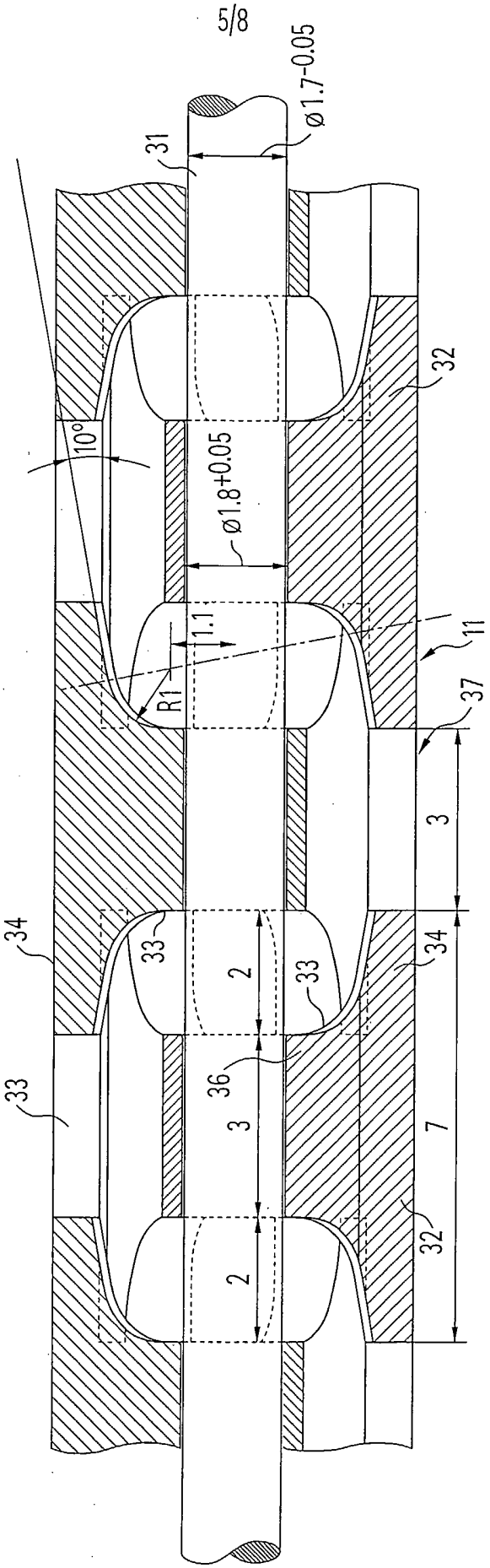



Fig. 7

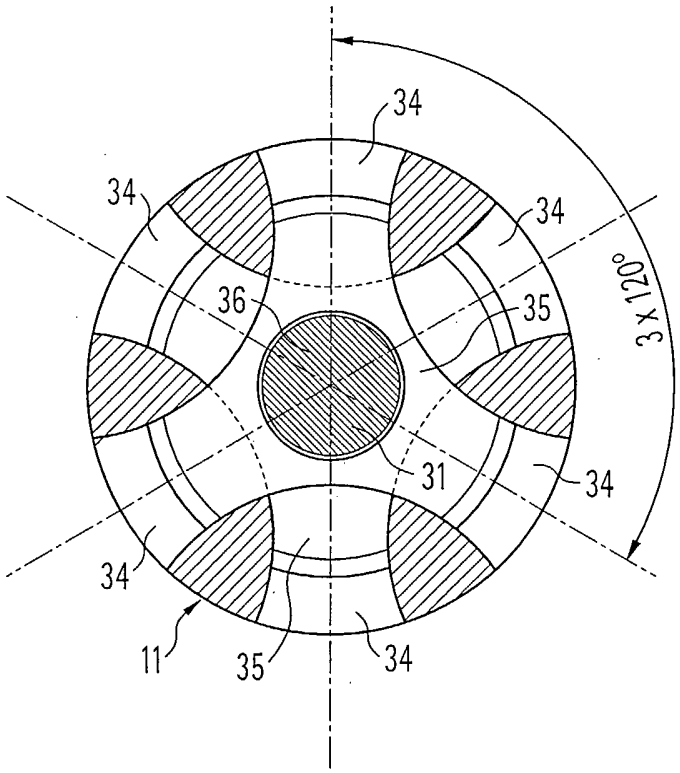



Fig. 8

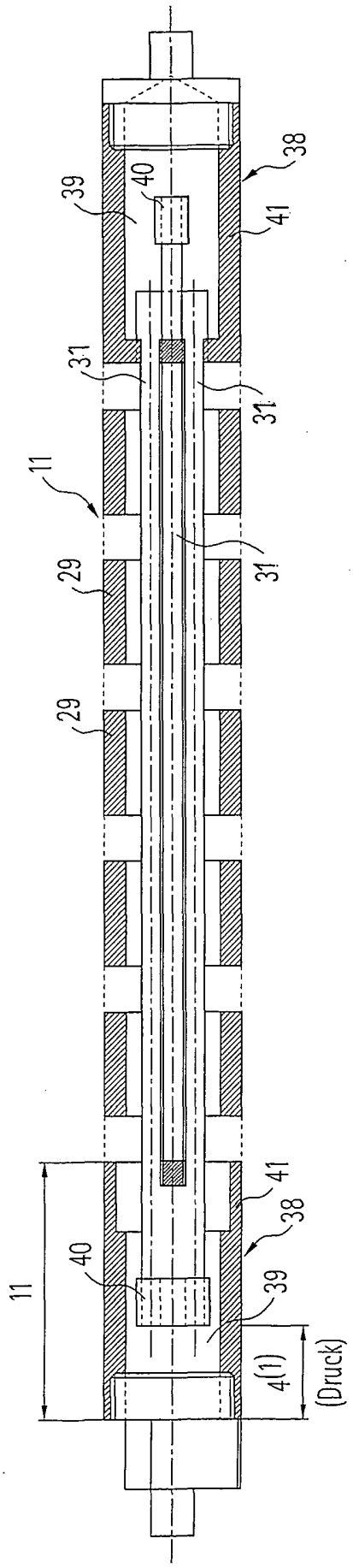
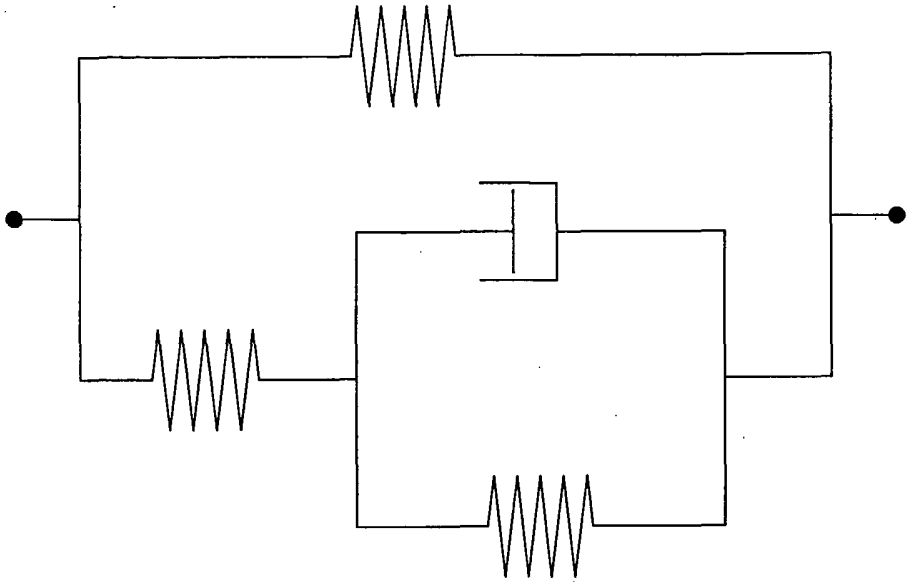
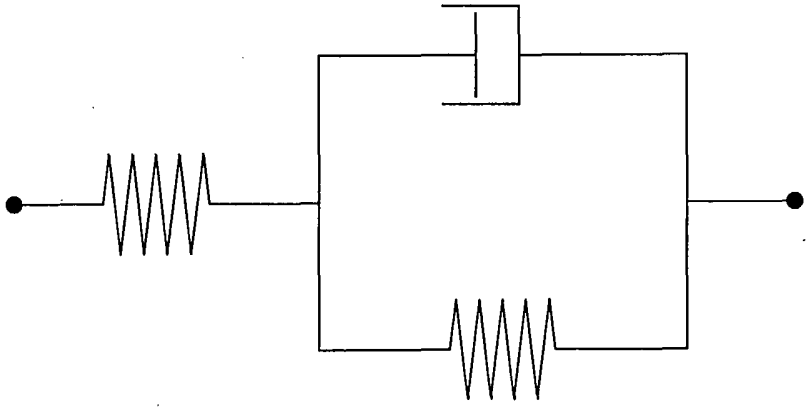


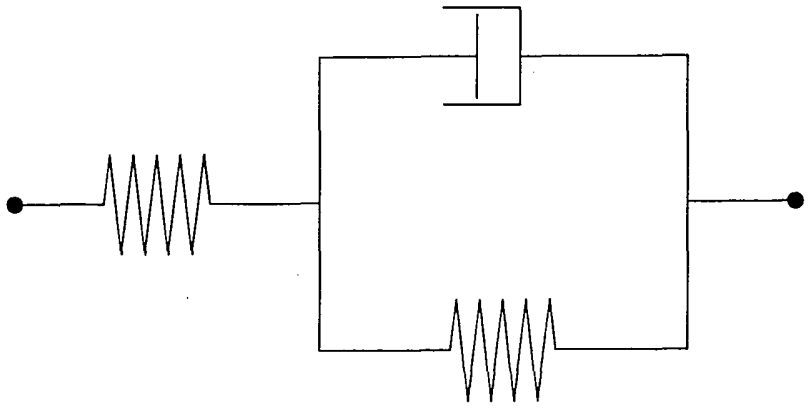

Fig. 9



Modell des Verbundes Metallspirale/Kunststoffstab



Modifiziertes Kelvin-Voigt Modell repräsentativ für Kunststoffstab



Kelvin-Voigt Modell

Fig. 10

# INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP2005/003962

**A. CLASSIFICATION OF SUBJECT MATTER**
IPC 7 A61B17/70

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)
IPC 7 A61B

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 practical, search terms used)
EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | FR 2 844 180 A (SPINEVISION)<br>12 March 2004 (2004-03-12)<br>abstract; figures 1-9<br>page 4, line 19 - page 5, line 2<br>page 10, lines 3-28<br>page 13, lines 1-14<br>----- | 1-9,11,<br>12,18 |
| X | FR 2 717 370 A (MOREAU PATRICE; ELBERG JEAN FRANCOIS)<br>22 September 1995 (1995-09-22)<br>abstract; figure 5<br>page 3, lines 13-17<br>page 6, lines 6-23<br>----- | 1-9,11,<br>12,30 |

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 29 June 2005 | 08/07/2005 |

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# INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP2005/003962

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
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| P,X | WO 2004/096066 A (KITCHEN, MICHAEL, S)<br>11 November 2004 (2004-11-11)<br>abstract; figures 1,2,5,7-9 | 1,2,12,<br>18 |
| X | FR 2 702 363 A (BIOMAT)<br>16 September 1994 (1994-09-16)<br>abstract; figures 1-4,6<br>page 2, lines 3-10<br>page 5, lines 3-9 | 1,2,6,7 |

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP2005/003962

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
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