

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
26 April 2007 (26.04.2007)

PCT

(10) International Publication Number
WO 2007/045892 A1

(51) International Patent Classification:
A61B 17/70 (2006.01) **A61B 17/00** (2006.01)

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(21) International Application Number:
PCT/GB2006/003907

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(22) International Filing Date: 20 October 2006 (20.10.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0521582.7 22 October 2005 (22.10.2005) GB

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

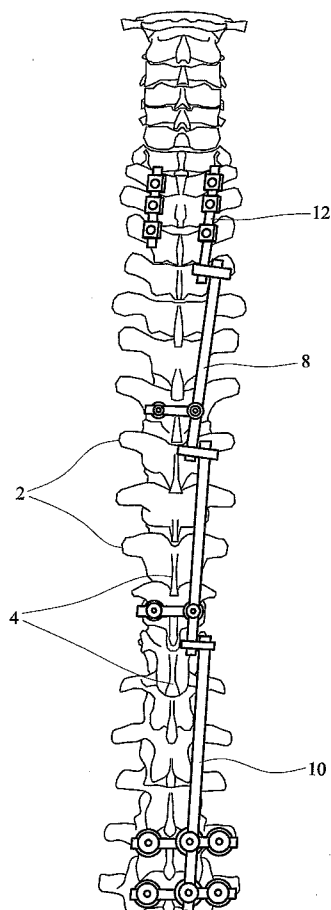
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(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),

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(54) Title: AN IMPLANT KIT FOR SUPPORTING A SPINAL COLUMN



(57) Abstract: An implant kit for supporting a spinal column comprises at least first and second support elements (8, 10, 12) for fixation to vertebrae of a spinal column, extending generally along the spinal column between spaced apart vertebrae. The kit includes a plurality of fixation devices for (i) fixing the support elements to one another in an end-to-end arrangement and (ii) fixing the support elements to the vertebrae. At least the first support element is formed from a material which exhibits shape memory properties .



European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *with international search report*

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AN IMPLANT KIT FOR SUPPORTING A SPINAL COLUMN

This invention relates to an implant kit for supporting a spinal column.

EP-A-470660 discloses apparatus for correcting the shape of a spinal column. The apparatus includes a rod which is formed from a nickel-titanium alloy which has been treated so that it exhibits shape memory properties, in bending or in torsion or both. Articles formed from shape memory alloys can exhibit shape memory properties associated with transformations between martensite and austenite phases of the alloys. These properties include thermally induced changes in configuration in which an article is first deformed from a heat-stable configuration to a heat-unstable configuration while the alloy is in its martensite phase. Subsequent exposure to increased temperature results in a change in configuration from the heat-unstable configuration towards the original heat-stable configuration as the alloy reverts from its martensite phase to its austenite phase. The transformation from austenite to martensite on cooling begins at a temperature known as the M_s temperature, and is completed at a temperature known as the M_f temperature. The transformation of martensite to austenite upon heating begins at a temperature known as the A_s temperature and is complete at a temperature known as the A_f temperature.

The rod of the apparatus disclosed in EP-A-470660 is fastened to a patient's vertebrae while in the configuration from which it has to recover. The temperature of the rod is then increased so that it is greater than the A_s temperature of the alloy. The rod then recovers towards its heat-stable configuration, applying a corrective force to the spinal column.

It can be important to select a rod having configurations both before and after recover which are suitable for the particular patient, having regard to the nature of the deformity of the spinal column which is to be corrected. Variations between patients can require variations in features such as rod length, rod curvature, and the location of curvature along the length of the rod. It is not feasible for the curvature or the length of a rod to be changed after manufacture. Accordingly, it can be necessary to supply a large inventory of rods to a surgeon in order for him to be able to optimise the fit of a rod to a particular patient.

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The present invention provides an implant kit for supporting a spinal column, which comprises at least first and second support elements for fixation to vertebrae of a spinal column in which at least the first support element is formed from a material which exhibits shape memory properties.

5 Accordingly, in one aspect, the invention provides an implant kit for supporting a spinal column, which comprises:

- a. at least first and second support elements for fixation to vertebrae of a spinal column, extending generally along the spinal column between spaced apart vertebrae,
- 10 b. a plurality of fixation devices for (i) fixing the support elements to one another in an end-to-end arrangement and (ii) fixing the support elements to the vertebrae,

in which at least the first support element is formed from a material which exhibits shape memory properties.

15 The kit of the invention has the advantage that it enables variations between patients to be accommodated with a smaller inventory than is required when a single rod is provided to extend over the length of a patient's spinal column. For example, the effective length of a spinal support assembly can be varied by changing the length of one of the support elements, preferably the second support element by cutting it, or by interchanging the
20 second support element for another element.

The kit of the invention can be used to provide an implant which optimised to suit the requirements of an individual patient by selection of an appropriate first support element and selection of an appropriate second support element. It might be for example that the maximum correction is required in the region of the spinal column in which the first
25 support element is to be implanted. The region of the spinal column in which the second support element is to be implanted might be relative free of deformity which is to be corrected, the second support element being used to provide support for the first support element.

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The first and second support elements can differ from one another by features which include one or more of material, physical properties (for example modulus, elastic limit, etc, which might for example be introduced through different processing techniques), dimensions (especially cross-sectional size (for example diameter when the cross-sectional shape is circular, or width when it is square or rectangular)), and cross-sectional shape (for example rounded, or polygonal etc as discussed below).

One or more support elements can be formed from a shape memory alloy. The alloy can be treated so that it is implanted while in the martensite phase. The treatment of the alloy can be such that its A_s and A_f temperatures are between ambient temperature and body temperature (37°C), so that the alloy is fully austenite phase at body temperature (for example by virtue of the A_f temperature being less than body temperature, for example about 32°C). This allows the surgeon to make use of the thermally initiated shape recovery properties of the alloy, in which the support element is implanted in the body in the martensite phase, which is stable at ambient temperature. On implantation, the element is exposed to body temperature which leads to the phase of the alloy transforming from martensite to austenite. The element will then tend towards a configuration from which it was transformed while in the martensite phase, applying corrective forces to a patient's vertebrae.

A support element which is formed from a shape memory alloy can apply corrective forces by virtue of the enhanced elastic properties that are available from such materials. Shape memory alloys can exhibit enhanced elastic properties compared with materials which do not exhibit martensite-austenite transformations and it is these properties that the present invention is concerned with in particular. The nature of superelastic transformations of shape memory alloys is discussed in "Engineering Aspects of Shape Memory Alloys", T W Duerig et al, on page 370, Butterworth-Heinemann (1990). Subject matter disclosed in that document is incorporated in this specification by this reference to the document. A principal transformation of shape memory alloys involves an initial increase in strain, approximately linearly with stress. This behaviour is reversible, and corresponds to conventional elastic deformation. Subsequent increases in strain are accompanied by little or no increase in stress, over a limited range of strain to the end of the "loading plateau".

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The loading plateau stress is defined by the inflection point on the stress/strain graph. Subsequent increases in strain are accompanied by increases in stress. On unloading, there is a decline in stress with reducing strain to the start of the "unloading plateau" evidenced by the existence of an inflection point along which stress changes little with reducing strain. At the end of the unloading plateau, stress reduces with reducing strain. The unloading plateau stress is also defined by the inflection point on the stress/strain graph. Any residual strain after unloading to zero stress is the permanent set of the sample. Characteristics of this deformation, the loading plateau, the unloading plateau, the elastic modulus, the plateau length and the permanent set (defined with respect to a specific total deformation) are established, and are defined in, for example, "Engineering Aspects of Shape Memory Alloys", on page 376.

A preferred way in which non-linear superelastic properties can be introduced in a shape memory alloy involves cold working the alloy by one of several deformation methods, for example, swaging, drawing, pressing, stretching or bending. The cold working step is followed by an annealing step at a temperature less than the recrystallization temperature of the alloy, for a time sufficient to cause dislocations to rearrange, combine and align themselves (so-called "recovery" processes). The resulting recovered dislocation structure should ideally be dense enough to make plastic deformation difficult, but not so dense as to prevent the martensite phase from transforming upon the application of a load, and growing in a relatively unimpeded manner.

Since many preferred superelastic alloys are thermally unstable in the temperature range in which these recovery processes occur, a second unavoidable result of this recovery heat treatment step is to age the material, that is to cause Ni-rich particles to precipitate, having the effect of enriching the matrix phase in titanium, and thus increasing the transformation temperatures (including the A_f temperature). Optimum superelastic properties are only realized when using shape memory alloys above the A_f temperature, though it should be noted that some indications of superelasticity are observed above the A_s temperature (typically 2 to 20°C below A_f). Thus a second requirement for this recovery heat treatment is that A_f not be increased above the temperature at which the alloy is to be used.

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Practically speaking this places upper limits on the time and temperature which can be used in the recovery heat treatment.

When it is desired only to rely on the superelastic properties of an alloy without any contribution from any thermally initiated shape memory effect, the alloy should by
5 processed so that its A_f temperature is below temperatures to which the alloy is likely to be subjected during implantation, that is preferably below about ambient temperature. For example, the A_f temperature might be not more than about 20°C.

A particularly preferred kit according to the invention includes a first support element which is formed from a shape memory alloy which has been treated so that it exhibits
10 thermally initiated shape recovery properties, and a second support element which is formed from a shape memory alloy which has been treated so that it exhibits enhanced elastic properties as discussed above. Such alloys can differ from one another in the characteristic transformation temperatures of the alloys: the alloy of the first support element should preferably have A_s and A_f temperatures which are between ambient
15 temperatures to which the element is exposed prior to and during implantation and body temperature, and the alloy of the second support element should have an A_f temperature which is below both ambient temperatures to which the element is exposed prior to and during implantation and body temperature.

Another preferred kit according to the invention includes a first support element which is
20 formed from a shape memory alloy which has been treated so that it exhibits enhanced elastic properties as discussed above, and a second support element which is formed from a metal which does not exhibit shape memory properties (whether enhanced elastic properties or thermally initiated shape recovery properties). The second support element can be relied on in portions of the vertebral column to minimise relative movement
25 between the vertebrae so that the column is stabilised in those portions. This can be with a view to promoting fusion between vertebrae. The first support element can be relied on to allow flexing of the vertebral column in portions where stabilisation is not required.

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A further preferred kit according to the invention includes a first support element which is formed from a shape memory alloy which has been treated so that it exhibits thermally initiated shape recovery properties, and a second support element which is formed from a metal which does not exhibit shape memory properties (whether enhanced elastic properties or thermally initiated shape recovery properties). The second support element can be relied on in portions of the vertebral column to minimise relative movement between the vertebrae so that the column is stabilised in those portions. This can be with a view to promoting fusion between vertebrae. The first support element can be relied on to exert corrective forces on a vertebral column over time.

It is often the case that a device is to be used in a shape other than that which can be practically produced by cold working processes. For example, a straight wire can be conveniently produced by cold drawing, but a wire loop or other formed shape cannot be. In this case, it is customary to form the drawn, cold worked wire into the desired "heat stable" shape, to constrain the wire in that shape, and then to perform the above described recovery heat treatment to "shape set" the component. In this case the final annealing operation has two purposes: to adjust the superelastic properties of the alloy, and to properly set the shape of the article. The time and temperature of this heat treatment step are critical. If held too long at temperature, the material over-ages, causing the A_f temperature to rise above the application temperature. If the annealing temperature is too short, or the temperature too low, the shape will be insufficiently formed, and too much of the original dislocation structure will remain to allow free martensite movement. This "forming" treatment may introduce still further cold work into the part, but that cold work is usually small compared to that introduced into the wire by drawing. Moreover, forming operations are often not uniform, and thus forming itself is not generally a convenient way to introduce cold work.

Articles of complicated shape require extensive forming and are very difficult to produce according to the above process. If the forming process causes strains which are too severe, the article will fracture as it is heated to the shape setting and recovery temperature (one is able to restrain the formed article, but cannot maintain its shape during the heating process without causing fracture). It is possible to overcome this problem by performing a series of

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smaller, intermediate shape setting operations which accumulate to provide the desired final shape, but unfortunately each of these shape setting operations requires sufficient annealing time to allow the material to soften, in preparation for the next. When accumulated, these heat treatments cause a cumulative ageing effect that can cause the A_f temperature to rise beyond the expected service temperature (37°C for most medical applications, for example).

It is also known that one can introduce superelasticity by solution treating and ageing, abandoning all attempts to retain cold work. Although this approach resolves the above problems, it leads to inferior superelastic properties, producing articles that are susceptible to fatigue and storage problems.

Examples of shape memory alloys which might be used in the first and possibly other support elements in the kit of the invention include nickel-titanium based alloys, especially the binary alloy which contains 50.8 at-% nickel. Suitable alloys include those which satisfy ASTM F2063-00. It will often be particularly preferred for both the first and second support elements to be formed from shape memory alloys, especially for each support element to be formed from shape memory alloys. Other metals which might be used to form support elements which do not exhibit shape memory properties include titanium and alloys thereof, for example Ti6Al4V alloys such as satisfy ASTM F136-02a or ASTM F1472-02a or both.

Materials which exhibit shape memory properties, other than alloys, can be used. For example, polymeric materials can be used. Shape memory properties can be imparted to polymeric materials by forming them in a desired ultimate shape (for example by moulding), crosslinking the material, heating the material to a temperature at which it softens, deforming the material while soft and restraining the material in the deformed configuration while it cools. The material will tend to revert towards the initial "as formed" configuration when reheated. Examples of suitable polymeric materials which can be used in this way include oligomers, homopolymers, copolymers and polymer blends which include, as monomers, L-, D- or D/L-lactide (lactic acid), glycolide (glycolic acid), ethers, ethylene, propylene and other olefins, styrene, norbornene, butadiene, poly-

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functional monomers such as acrylates, methacrylates, methyl acrylates, and esters such as caprolactone. The use of such polymeric materials in related applications is disclosed in WO-02/34310.

The first support element will generally be longer than the second support element. The first element will often be used to correct deformities in the thoracic region or in the lumbar region or both, where the range of motion that is available from the use of a shape memory alloy can be used to greatest advantage. The second support element can be arranged for implantation in any of the sacral, lumbar, thoracic and cervical regions. Additional support elements (for example third and optionally fourth support elements) can be included, for example so that separate support elements can be provided to extend into regions other than the region in which the first support element is provided.

The use of a material for the second support element which is not made from a shape memory alloy has the advantage that the length of the second support element can be adjusted to suit the requirements of a particular patient by cutting. Overall, the inventory that has to be maintained to enable procedures to be performed on a wide range of patients can be less than is required when the implant kit includes a single support element which is intended to extend over the full length of the patient's spinal column.

Preferably, the ratio of the length of the first support element to that of the second element is at least about 1.2, more preferably at least about 1.5, especially at least about 2.0, for example at least about 2.5.

The length of the first support element is preferably at least about 50 mm, more preferably at least about 75 mm, for example at least about 100 mm, and possibly 150 mm or more, for example up to about 300 mm. The length of the second support element is preferably at least about 30 mm, more preferably at least about 50 mm, for example at least about 80 mm, and possibly 120 mm or more. The length of the second support element might be not more than about 120 mm, preferably not more than about 100 mm, for example not more than about 80 mm, possibly not more than about 50 mm.

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The angle between the end portions of the first support element can be greater than the angle between the end portions of the second support element, the angles being measured prior to implantation. The angles are measured between the normals at the ends of the support elements. Preferably, the difference between (a) the angle between the end portions of the first support element and (b) the angle between the end portions of the second support element is at least about 20°, more preferably at least about 25°, especially at least about 30°. It can be appropriate for a support element which is to be implanted in the lumbar region of the spine to have a larger angle between its end portions compared with a support element which is intended for implantation in the thoracic or other region of the spine.

Preferably, the first support element is capable of recoverable deformation from its original undeformed configuration (from which it had previously been deformed) such that the angle between its ends changes through at least about 20°, more preferably at least about 25°, especially at least about 30°. Recoverable deformation is deformation that can be recovered substantially completely back to the undeformed configuration when applied stress is removed, or otherwise when allowed to recover (for example as a result of heating to allow a transformation to austenite phase).

Especially when the second support element is not formed from a material with shape memory properties, the recoverable deformation from its undeformed configuration will generally be less than that which is available in the first support element.

The first support element or the second support element or both will preferably be a rod, especially with a solid cross-section. A rod support element can be hollow along at least part of its length. One or more of the support elements can be a plate.

The cross-sectional area of each support element will often be approximately constant over at least most of the length of the support element, with the possibility that the cross-section might vary in at least one end region to facilitate connection directly or indirectly to a vertebra at the end or to an adjacent support element. The cross-sectional area of the first support element can be different from the cross-sectional area of the second support

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element. For example, the cross-sectional area of the first support element or of the second support element might be at least about 10 mm², preferably at least about 20 mm², more preferably at least about 30 mm², for example about 40 mm². The difference between the cross-sectional areas of the first and second support elements might be at least about
5 3 mm², preferably at least about 5 mm², more preferably at least about 10 mm².

The cross-sectional shapes of the first and second support elements might be the same or might be different. One or both of the elements might have a rounded cross-sectional shape, especially circular. It can be preferred for an element sometimes to be non-circular to enable it to fit securely in a fastener in such a way that it can transmit torque to the
10 fastener. For example, the element can have at least one flat face. Polygonal (regular or irregular) shapes can be useful, for example with at least four faces, including square or rectangular or trapezoidal (when the element has four faces when viewed in cross-section), or with six or eight or more faces. An element which has a generally rounded cross-section might have a flat face.

15 The support elements are capable of being connected directly or indirectly to one another so that the kit provides a continuous support for a spinal column which extends continuously between the furthest apart ends of the furthest apart support elements. Fixation devices for connecting support elements of a kit for supporting a spinal column are known, for example as used in the ISOLA spinal support system which is manufactured
20 and sold by DePuy Spine Inc. That system includes a connector for spinal support rods in a side-by-side arrangement which is known as a tandem rod connector, and a connector for spinal support rods in an end-to-end arrangement which is known as a closed dual rod connector (wedding band).

25 Preferably, at least one of the fixation devices includes (a) a first connection feature by which the device can be connected to the first support element (generally towards its end), and (b) a second connection feature by which the device can be connected to the second support element (generally towards its end). Suitable fixation devices for connecting support elements of a kit can connect the elements in an end-to-end arrangement in the manner of a butt joint. Suitable fixation devices for connecting support elements of a kit

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can connect the ends of the element in a side-by-side arrangement in the manner of a lap joint. Suitable fixation devices for connecting support elements can comprise a housing with respective bores for receiving the ends of the support elements. The bores can be axially aligned and communicate with one another when the support elements are to be
5 connected in a butt joint arrangement. Particularly when the support elements are connected with their ends non-aligned, the effective length of the implanted kit can be adjusted by moving the end of one or other of the support elements relative to the housing.

Fixation devices which include a housing with at least one bore for a support element can include a locking part by which the support element can be locked into the housing. A
10 particularly preferred locking part is a threaded fastener which is received in a threaded bore in the housing.

It can be preferred for at least one of the fixation devices to comprise a socket portion which is located at or towards one end of one of the support elements, into which the end of the other of the support elements can be inserted in order to fix the support elements to
15 one another in an end-to-end arrangement. The said socket portion can be permanently attached to the support element on which it is located, for example by being machined or cast as one part with the support element, or by permanent fixing thereto, for example by welding. The provision of a permanently attached socket portion on one of the support elements can be preferred in the case of the second support element when it is formed from
20 a material which does not exhibit shape memory properties.

A support element can have socket portions at each of two opposite ends.

A fixation device which includes connection features for the first and second support elements can include a third connection feature by which the device can be fixed to a vertebra. A connection feature for fixation to a vertebra can comprise a hook, or a bone
25 screw which is arranged to extend through an opening in the housing. Connection features of this general type for fastening spinal support elements to a patient's spinal column are known.

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A connection feature for fixation to a vertebra can include a lateral arm which extends across the vertebra from the side of the spinal process on which the support elements are located to the other side of the spinal process. The transverse arm can then be fastened to the vertebra by means of a hook or a bone screw.

- 5 The kit can include a fixation device which includes (a) a first connection feature by which the device can be connected to one of the first and second support elements, and (b) a second connection feature by which the device can be fixed to a vertebra.

10 A fixation device which includes a housing with a bore into which a support element can extend will generally be formed from a metal, as is known. Suitable metals include certain stainless steels, and titanium and its alloys.

A fixation device which includes a feature by which the device can be fixed to a vertebra will generally be formed from a metal, as is known. Suitable metals include certain stainless steels, and titanium and its alloys.

15 The kit of the invention can be used in dynamic spinal support systems, for example to provide support over thoracic, lumbar and sacral vertebrae respectively. A first support element can be used to provide support in the thoracic region which is formed from a material which does not exhibit shape memory properties. This can stabilise the spine in the thoracic region and promote fixation. A second support element can be used to provide support in the lumbar region, which is formed from a shape memory material which
20 exhibits enhanced elastic properties. This can provide flexibility allowing the spine to flex in the lumbar region. A third support element can be used to provide support in the sacral region which is formed from a material which does not exhibit shape memory properties. This can stabilise the spine in the sacral region and promote fixation.

25 The kit of the invention can be used in the treatment of scoliosis. A first support element can be used to provide support in the lumbar region which is formed from a material which does not exhibit shape memory properties. This can stabilise the spine in the lumbar region and promote fixation. A second support element can be used to provide support in the

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thorocolumbar region, which is formed from a shape memory material which exhibits thermally initiated shape recovery properties. This can exert corrective forces on the spine over time. A third support element can be used to provide support in the upper thoracic region, which is formed from a shape memory material which exhibits enhanced elastic properties. This can provide flexibility allowing the spine to flex in the upper thoracic region.

The kit of the invention can be used in the treatment of trauma damage to the spine. A first support element can be used to provide support in the region of the spine which has been damaged, which is formed from a material which does not exhibit shape memory properties. This can stabilise the spine in the damaged region. Further support elements can be used to provide support in adjacent regions, which are formed from a shape memory material which exhibits enhanced elastic properties.

The kit of the invention can be used in the treatment of a spine which is affected by a degenerative disease. A first support element can be used to provide support in the diseased region, which is formed from a shape memory material which exhibits thermally initiated shape recovery properties. This can exert corrective forces on the spine over time. Further support elements can be used to provide support in adjacent regions, which are formed from a shape memory material which exhibits enhanced elastic properties.

Embodiments of the invention will now be described by way of example with reference to the accompanying drawings, in which:

Figure 1 shows a spinal column with spinal support elements of a spinal support kit according to the invention fastened to it by means of fixation devices.

Figure 2 shows features of spinal support elements which can be used in the kit of the invention.

Figure 3 shows fixation devices for connecting spinal support elements to one another.

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Referring to the drawings, Figure 1 shows a spinal column viewed posteriorly which comprises a plurality of vertebrae 2. The posteriorly extending spinal process 4 is visible. The present invention provides a kit which includes a plurality of spinal support elements 6, each in the form of a rod, which can support the spinal column and, in particular, apply forces to the vertebrae to correct deformities.

The kit comprises two support elements 8 which are intended for use in the thoracic region which are formed from a shape memory alloy which consists of 50.8 at-% nickel and the balance (apart from impurities) titanium. The alloy has been treated so that its A_f temperature is about 20°C. This means that the alloy is able to exhibit superelastic properties, allowing it to be deformed in order to be fitted to the vertebrae. Once deformed (for example by as much as 8%), the element tends towards its configuration prior to deformation, applying forces to the vertebrae to which it is attached.

The kit further includes support elements 10 which are formed from titanium which are intended for use in the lumbar region.

The kit also includes support elements 12, also formed from titanium, which are intended for use in the cervical region.

Support elements which are formed from titanium have the advantage that they can be cut to a desired length more easily than is the case with support elements which are formed from a nickel-titanium based alloy.

The kit includes fixation devices by which the spinal support elements can be fastened to the patient's vertebrae. The support elements are fastened to the vertebrae by means of bone screws. Each bone screw passes through an aperture in the base of a channel member which is dimensioned to receive a spinal support element between the side walls of the channel member. The internal side walls of the channel member are threaded to engage the threads on the circumferential wall of a screw which can be located within the channel member to retain the support element therein. This approach to fixation of spinal support

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elements is known, for example from the implant system which is sold by DePuy Spine Inc under the trade mark EXPEDIUM.

Figure 2a shows cross-sections through spinal support elements which can be used in the kit of the invention. Suitable support elements can have shapes when viewed in cross-section which are hexagonal, circular, half-round (with a flat face), trapezoidal and square. The support elements will generally have the same cross-section from one end to the other end. However, it will often be appropriate for the cross-section to vary in at least some parts, especially at the ends of the rods. Reasons for changing the cross-section include ease of fixation in the fixation devices, and the desired degree to which torsional forces (when required) can be transmitted to fixation devices to which the support elements are attached.

Suitable cross-sectional areas for the support elements include about 12 mm², 20 mm², and 28 mm².

Figure 2b shows schematically the range of shapes of support elements which might be used in the kit of the invention. Examples of useful lengths of the rods include 80 mm, 120 mm and 160 mm (or other lengths within and beyond this range). The support elements might be straight, or might define a Cobb angle of 18°, 42° or 50° (or other angles within and beyond this range).

Figure 3a shows a fixation device by which two support elements 30, 32 can be connected to one another side-by-side in a lap joint arrangement. In the illustrated embodiment, one of the support elements 30 has a square cross-section, at least at it end, and the other support element 32 has a round cross-section. The device comprises a housing 34 having two through bores 36 extending through it which are parallel. Each of the bores has a square cross-section so that the ends of the support elements are sliding fit therein.

The housing also has a pair of fixation bores formed in it extending generally perpendicular to the through bores 36. The fixation bores are threaded internally so that each of them can receive a fixation screw 40.

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In use, the ends of the support elements are inserted into respective ones of the through bores, and moved relative to the through bores until they are positioned appropriately having regard to the desired overall length of the implant. Each of the fixation screws 40 is then tightened in the housing so that it acts on the inserted end of the respective support element.

Figure 3b shows a fixation device of a commonly known type which can be used to fix a support element to bone tissue. The fixation device comprises a channel defined by side walls 46 and a base 48. A support element can be fitted into the channel between the side walls. The channel has a threaded shaft 50 extending from its base, which can be screwed into bone tissue. The configuration of the bone engaging thread is optimised as known.

The internal surfaces 52 of the side walls bear a thread, which can be engaged by a locking screw (not shown) to retain the support element in the channel, as known.

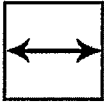
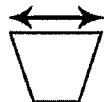
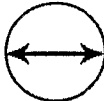
Figure 3c shows another fixation device of a commonly known type which can be used to fix a support element to bone tissue. The fixation device comprises a channel defined by side walls 60 and a base 62. A support element can be fitted into the channel between the side walls. The channel has a hook 64 on its base, which can engage bone tissue on a patient's vertebra, as known. A support rod 66 is located in the channel in the fixation device.

Examples of spinal support kits according to the invention are as follows:

EXAMPLE 1

Support elements

-17-

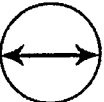
Spinal levels	Length (mm)	Cross-section shape	Cross-section dimensions (mm)	Material	A _f temperature (°C)	Tensile strength (MPa)
L5-L1	150		6.0	NiTi	15	551
T12-T4	200		5.0	NiTi	32	551
T3-C6	80		3.5	Ti	-	860

5 Fixation elements

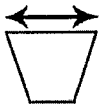
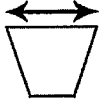
Spinal levels	Fixation elements
L5-L1	Pedicle screws
T12-T4	Pedicle screws
T3-C6	Hooks

10 EXAMPLE 2

Support elements

Spinal levels	Length (mm)	Cross-section shape	Cross-section dimensions (mm)	Material	A _f temperature (°C)	Tensile strength (MPa)
L3-L1	100		6.0	Ti	-	860

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Spinal levels	Length (mm)	Cross-section shape	Cross-section dimensions (mm)	Material	A _f temperature (°C)	Tensile strength (MPa)
T12-T4	200		4.5	NiTi	32	551
T3-T1	80		3.5	Ti	-	860

Fixation elements

Spinal levels	Fixation elements
L3-L1	Pedicle screws
T12-T4	Hooks
T3-T1	Pedicle screws

CLAIMS:

1. An implant kit for supporting a spinal column, which comprises:
- a. at least first and second support elements for fixation to vertebrae of a spinal column, extending generally along the spinal column between spaced apart vertebrae,
- b. a plurality of fixation devices for (i) fixing the support elements to one another in an end-to-end arrangement and (ii) fixing the support elements to the vertebrae,

in which at least the first support element is formed from a material which exhibits shape memory properties.

2. A kit as claimed in claim 1, which includes a first support element which is formed from a shape memory alloy which has been treated so that it exhibits thermally initiated shape recovery properties, and a second support element which is formed from a shape memory alloy which has been treated so that it exhibits enhanced elastic properties.

3. A kit as claimed in claim 1, which includes a first support element which is formed from a shape memory alloy which has been treated so that it exhibits enhanced elastic properties, and a second support element which is formed from a metal which does not exhibit shape memory properties.

4. A kit as claimed in claim 1, which includes a first support element which is formed from a shape memory alloy which has been treated so that it exhibits thermally initiated shape recovery properties, and a second support element which is formed from a metal which does not exhibit shape memory properties.

5. A kit as claimed in claim 1, in which the first support element is longer than the second support element.

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6. A kit as claimed in claim 1, in which the angle between the end portions of the first support element is greater than the angle between the end portions of the second support element, the angles being measured prior to implantation.

7. A kit as claimed in claim 6, in which the difference between (a) the angle between the end portions of the first support element and (b) the angle between the end portions of the second support element is at least about 20°.

8. A kit as claimed in claim 1, in which at least one of the fixation devices includes (a) a first connection feature by which the device can be connected to the first support element, and (b) a second connection feature by which the device can be connected to the second support element.

9. A kit as claimed in claim 8, in which the said fixation device includes a third connection feature by which the device can be fixed to a vertebra.

10. A kit as claimed in claim 1, in which at least one of the fixation devices comprises a socket portion which is located at or towards one end of one of the support elements, into which the end of the other of the support elements can be inserted in order to fix the support elements to one another in an end-to-end arrangement.

11. A kit as claimed in claim 10, in which the said socket portion is permanently attached to the support element on which it is located.

12. A kit as claimed in claim 1, in which at least one of the fixation devices includes (a) a first connection feature by which the device can be connected to one of the first and second support elements, and (b) a second connection feature by which the device can be fixed to a vertebra.

13. A kit as claimed in claim 1, in which the material of the first support element is different from the material of the second support element.

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14. A kit as claimed in claim 1, in which the shape of the first support element when viewed in cross section is different from the shape of the second support element when viewed in cross-section.

5 15. A kit as claimed in claim 1, in which the cross-section of at least one of the first and second support elements is non-round.

16. A kit as claimed in claim 1, in which the second support element is formed from a material which exhibits shape memory properties.

17. A kit as claimed in claim 1, in which the first support element is formed from a nickel-titanium based alloy.

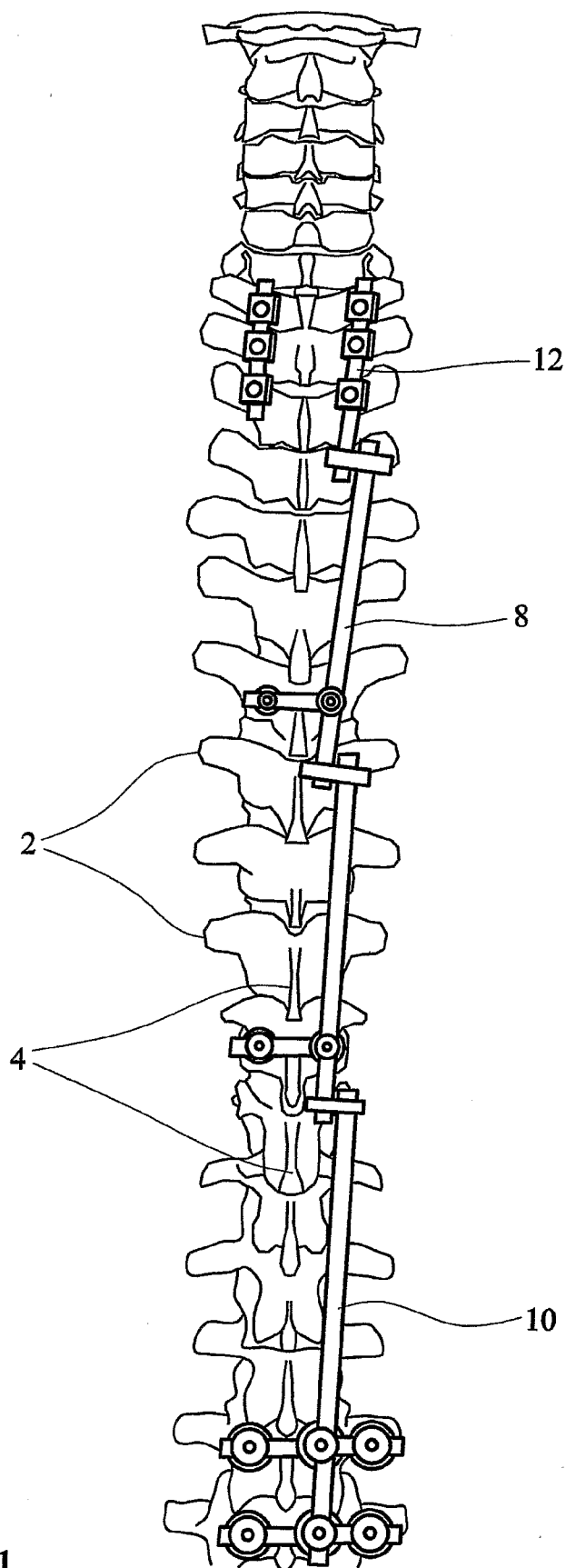


FIG. 1

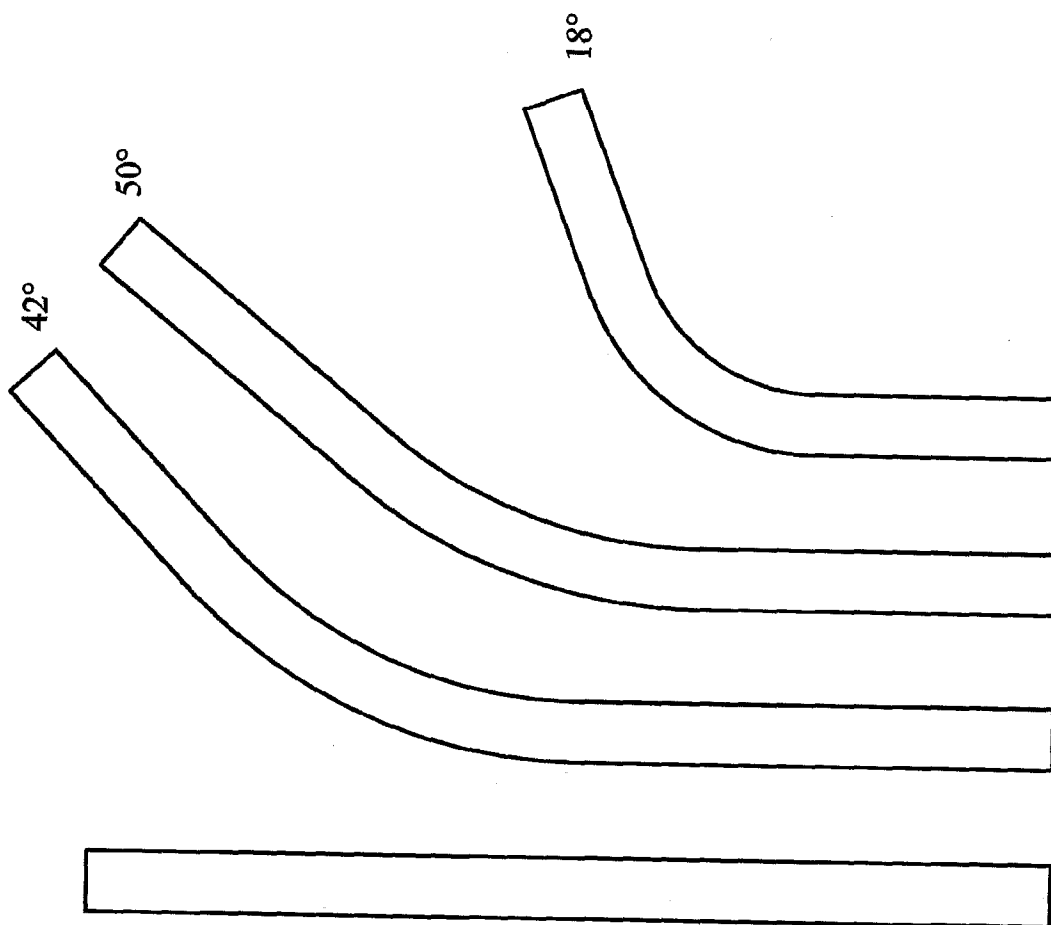


FIG. 2B

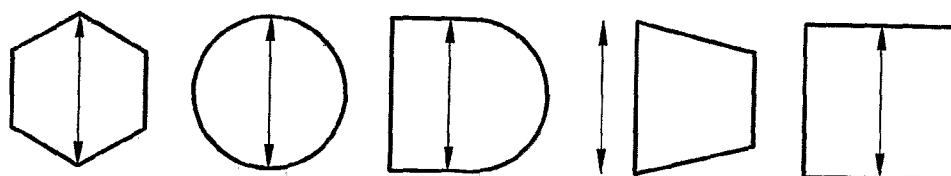


FIG. 2A

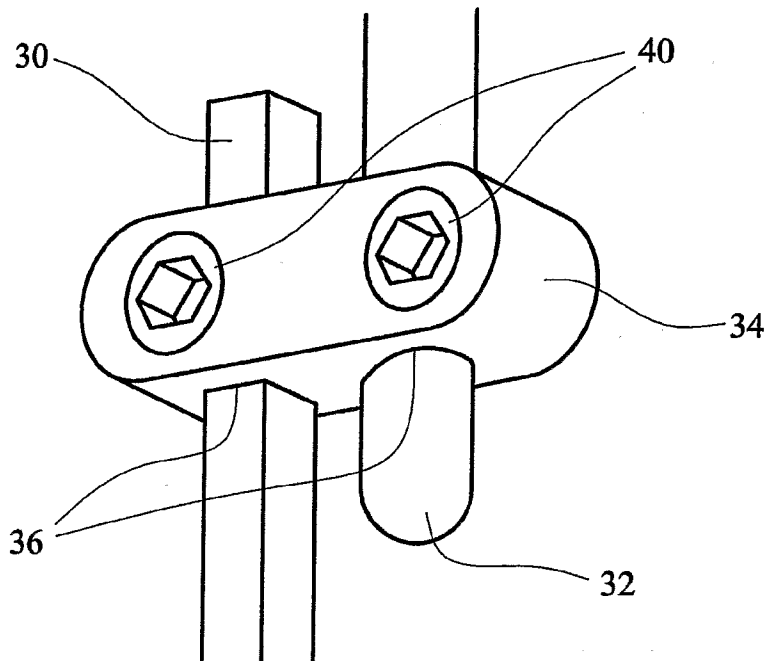


FIG. 3A

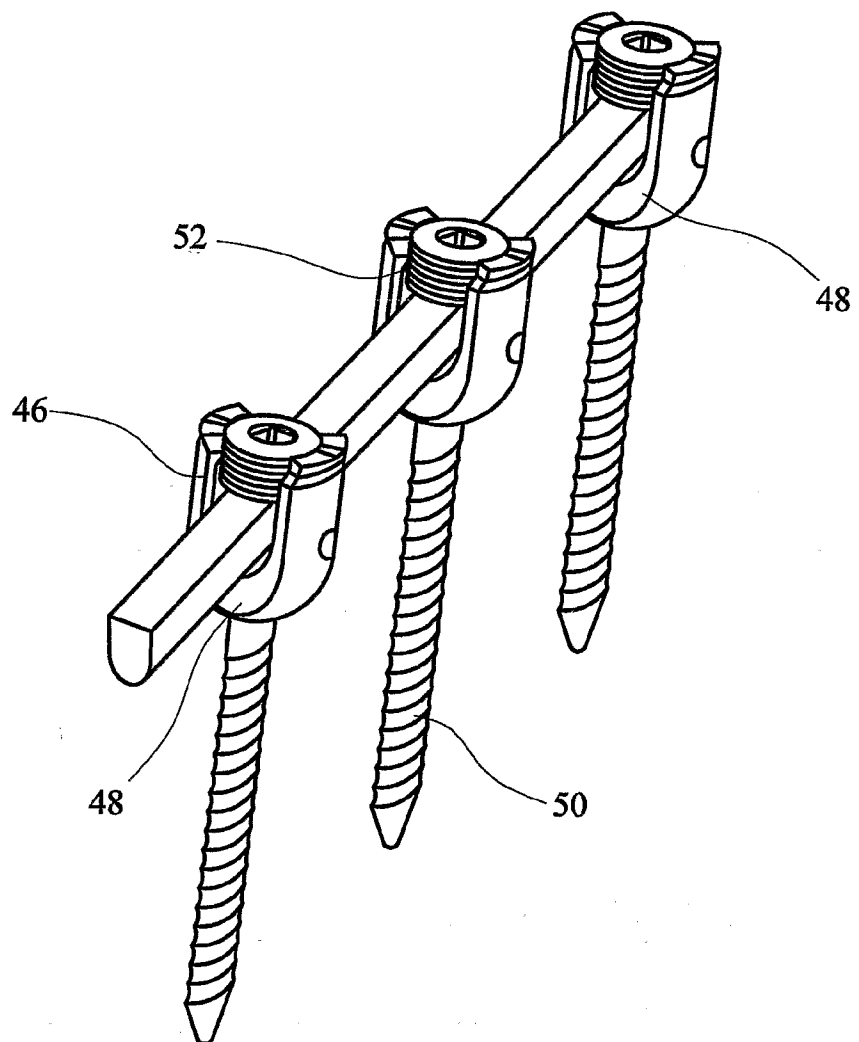


FIG. 3B

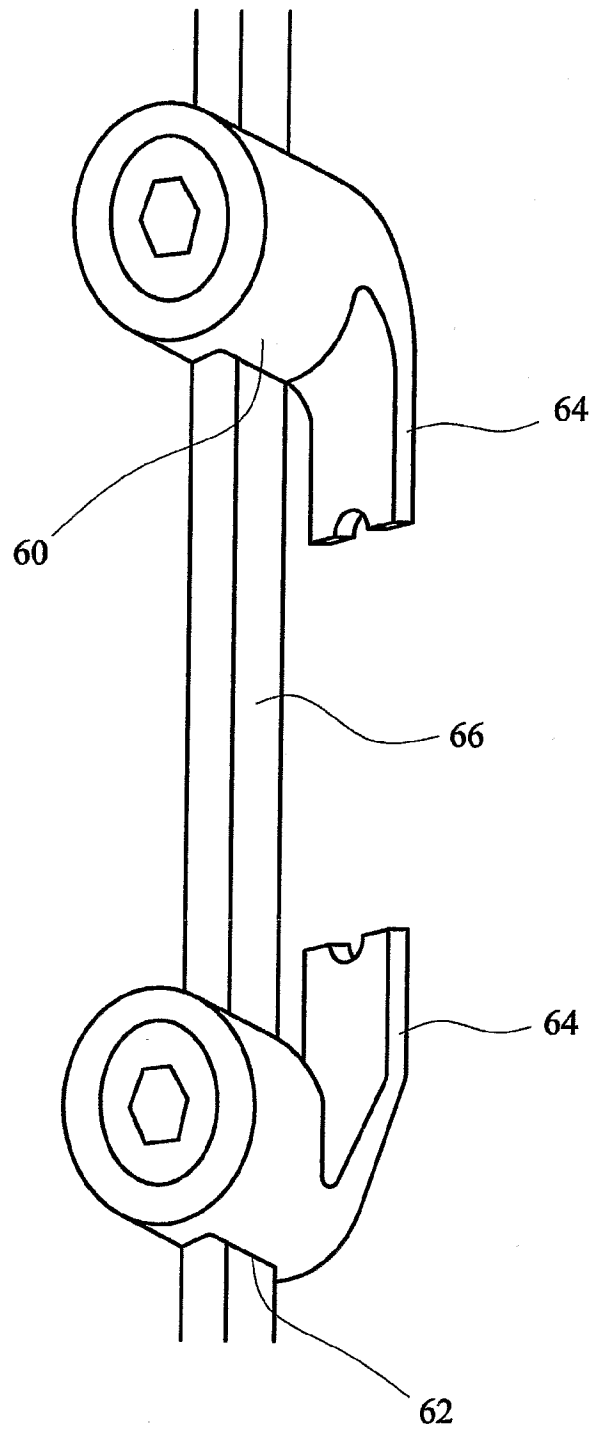


FIG. 3C

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2006/003907

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/70
ADD. A61B17/00

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)
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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 412 320 A (JOINT SOLUTIONS LTD [GB]) 28 September 2005 (2005-09-28) figures 1-3 claims 8,12,17,19,21,22 page 6 - page 9	1-5,8,9, 12-17
Y		6,7,10, 11
Y	US 2005/033295 A1 (WISNEWSKI PAUL [US]) 10 February 2005 (2005-02-10) figures 1-4 paragraphs [0024], [0025], [0028], [0031] - [0038], [0071]	1-8,10, 12-16
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☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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

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Date of the actual completion of the international search

18 January 2007

Date of mailing of the international search report

31/01/2007

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INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2006/003907

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
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Y	US 2005/228376 A1 (BOOMER MARK C [US] ET AL) 13 October 2005 (2005-10-13) figures 1A,1B paragraphs [0027], [0029], [0031]	10,11
P,X	WO 2006/101898 A (SDGI HOLDINGS INC [US]; BRUMFIELD DAVID L [US]) 28 September 2006 (2006-09-28) figures 1-3 page 5 - page 7 page 10, line 4 - line 11 page 11, line 19 - line 22	1-6,8, 10,12-17

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2006/003907

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			WO	2005102189 A1		03-11-2005
WO 2006101898	A	28-09-2006	US	2006229607 A1		12-10-2006